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A5R RAC

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US 4961725 A

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Online database: WPI

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# (54) Urinary incontinence control device

(57) The device, which internally retains the urine in the bladder until voluntary urination is required, comprises a catheter 12, 14, 15 for insertion in the urethra 1, a bladder balloon 4 and an inflatable balloon 16 within the catheter for simulating the sphincter. The balloon 16 is connected via tube 18 to a reservoir balloon for inflation/deflation, a pressure switch being provided for varying the inflation pressure from zero when full urine flow can occur to maximum when urine is retained. The control pressure can be pre-set by a nurse but a cam lever switch is also provided to allow the patient to voluntarily urinate. An electronic pressure sensor may be included for external electronic monitoring of balloon diameter/Charriere Size without disturbing the patient and means may also be included to prevent bacterial infection by the automatic venting of an irrigation spray tube 36 after each completed urination.

Fig. 1

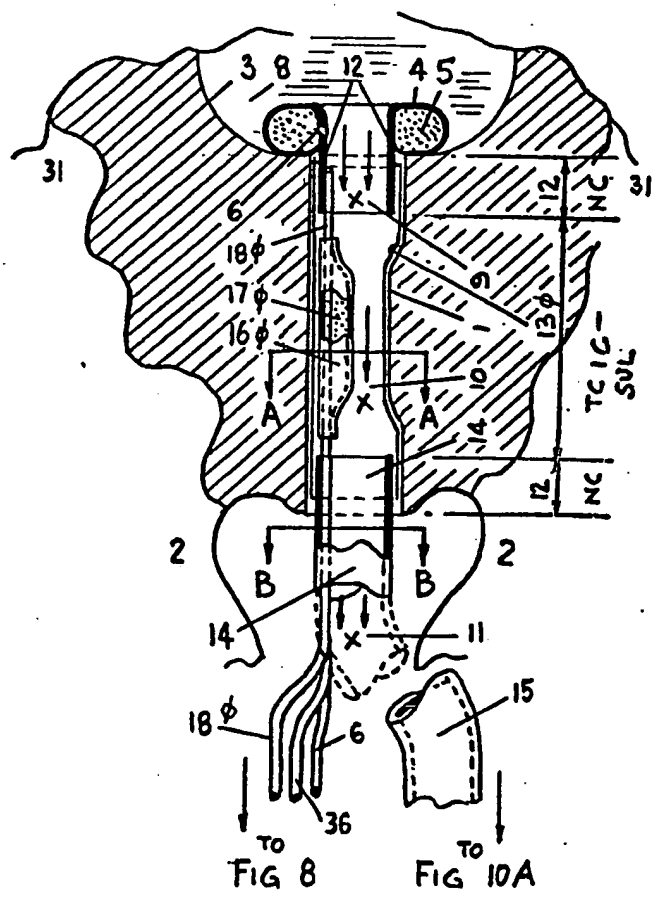



FIG 8 FIG 10A

GB 2 261 169 A

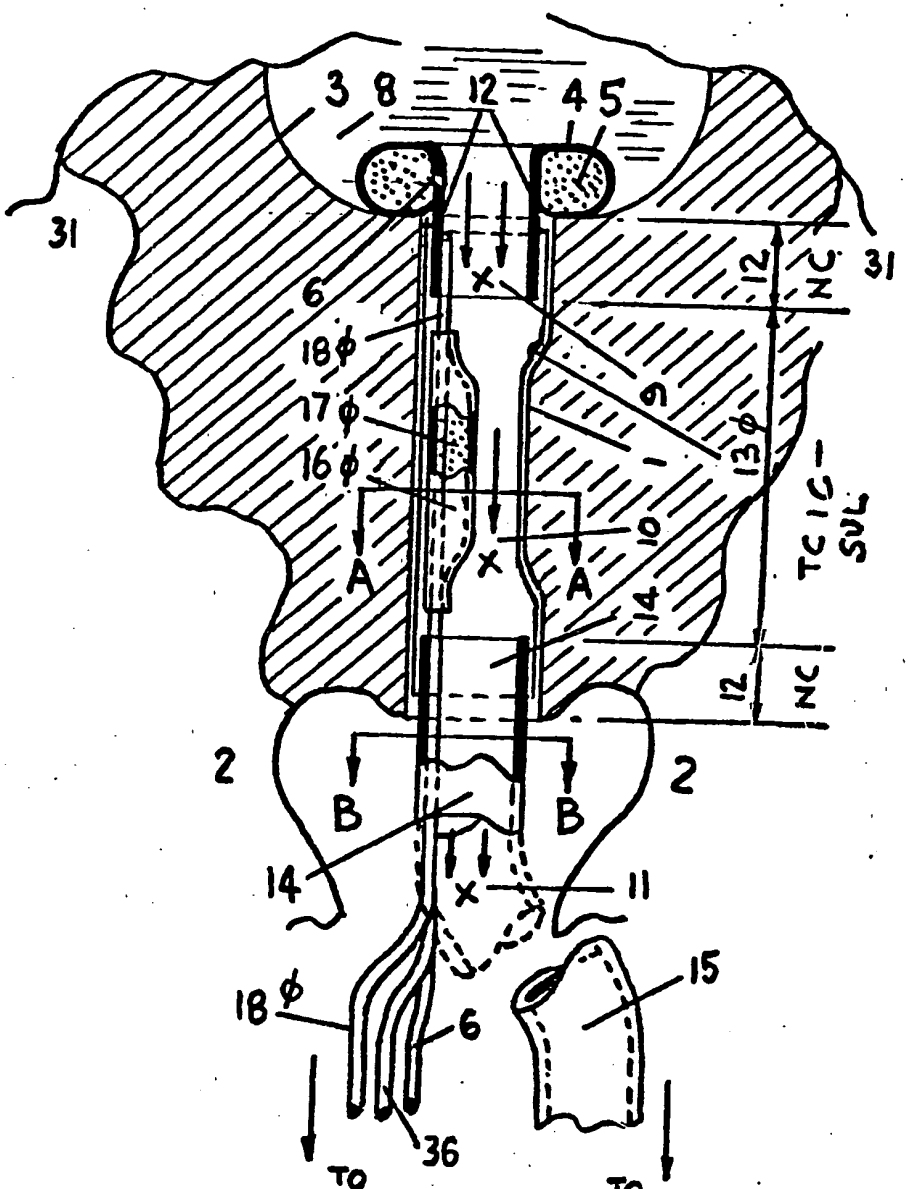

3
8
12
4
5
31
31
6
18φ
17φ
16φ
12
NC
9
13φ
TC IC-
SUL
10
A
A
X
14
12
NC
2
2
B
B
14
X
11
18φ
6
15
36
TO
TO

FIG 8 FIG 10A

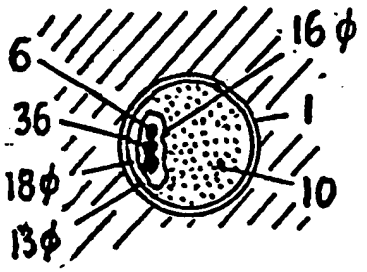



FIG 2
SECTION AA

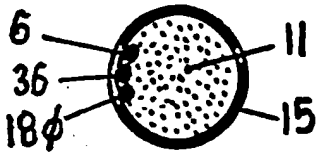



FIG 3
SECTION BB

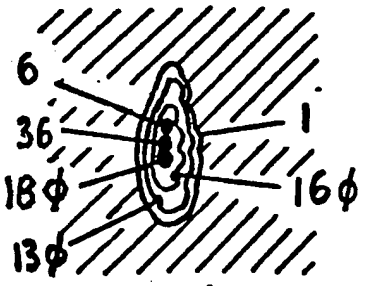



FIG 4
STAGE 1

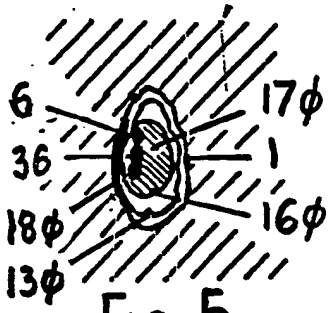



FIG 5
STAGE 2

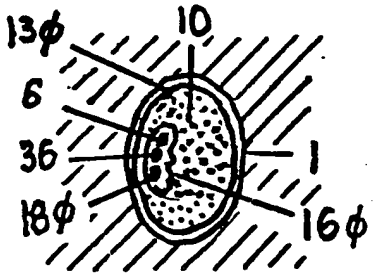



FIG 6
STAGE 3

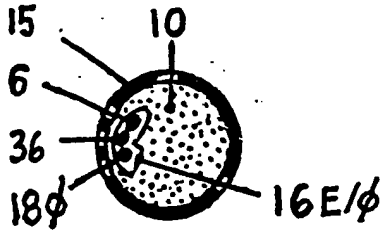



FIG 7
STAGE 4

FIG 9

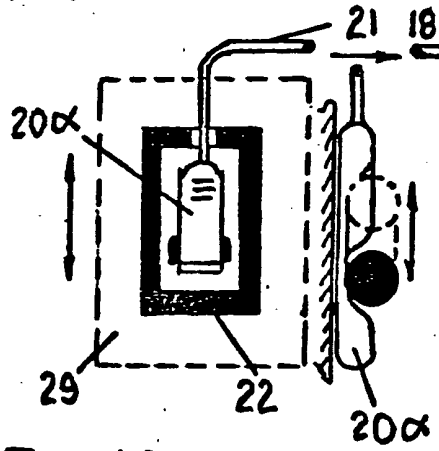



FIG 8

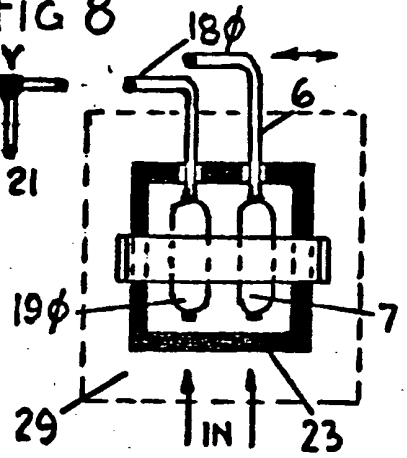



FIG 10A

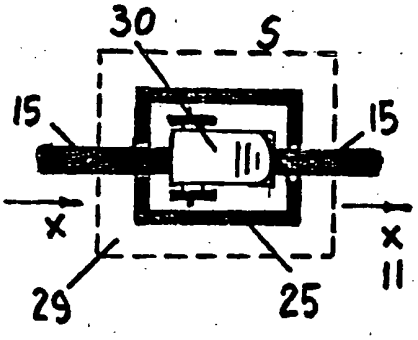



FIG 10B'

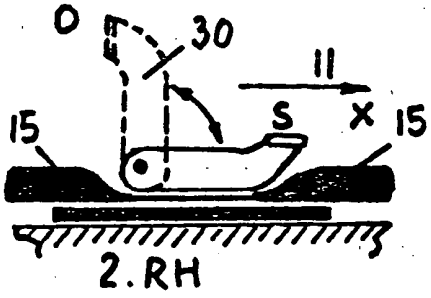
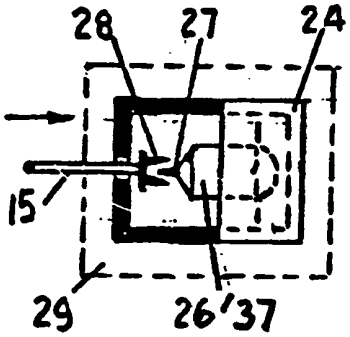



FIG 11



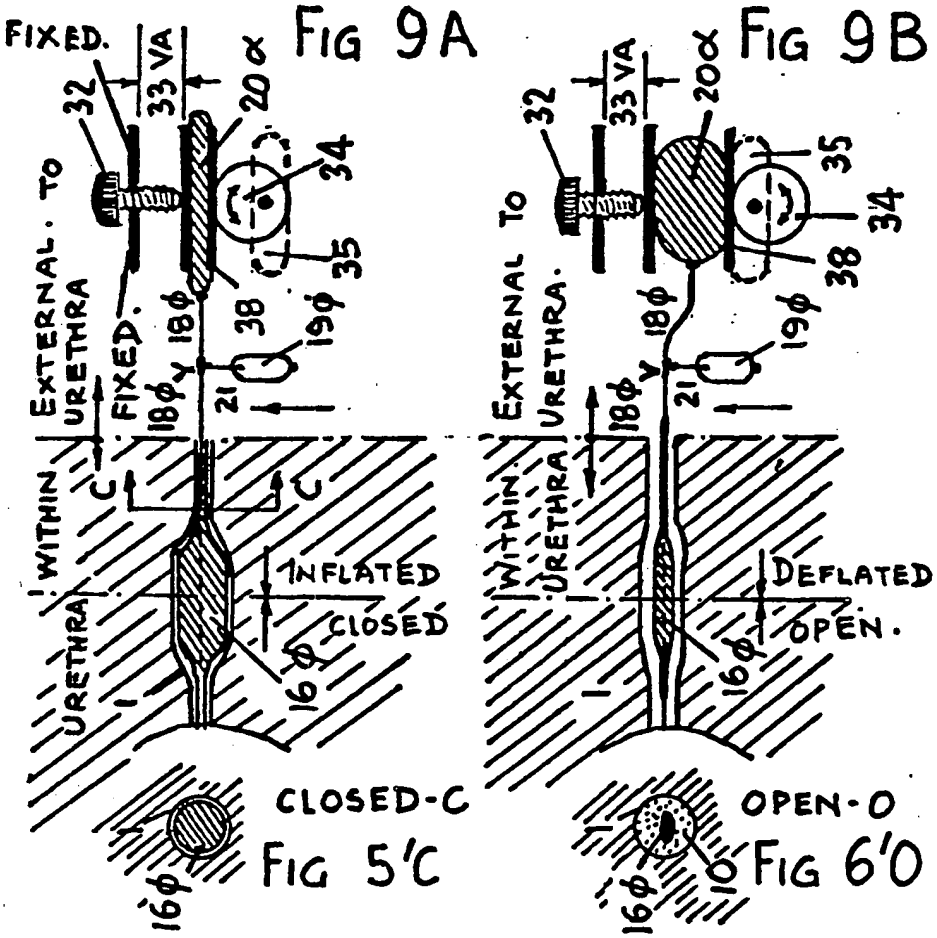



FIG 9A

FIG 9B

FIG 5'C

FIG 6'O

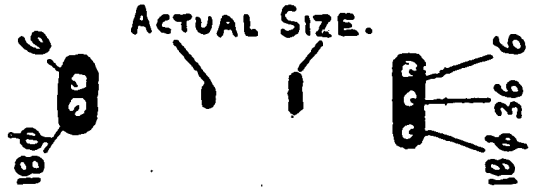
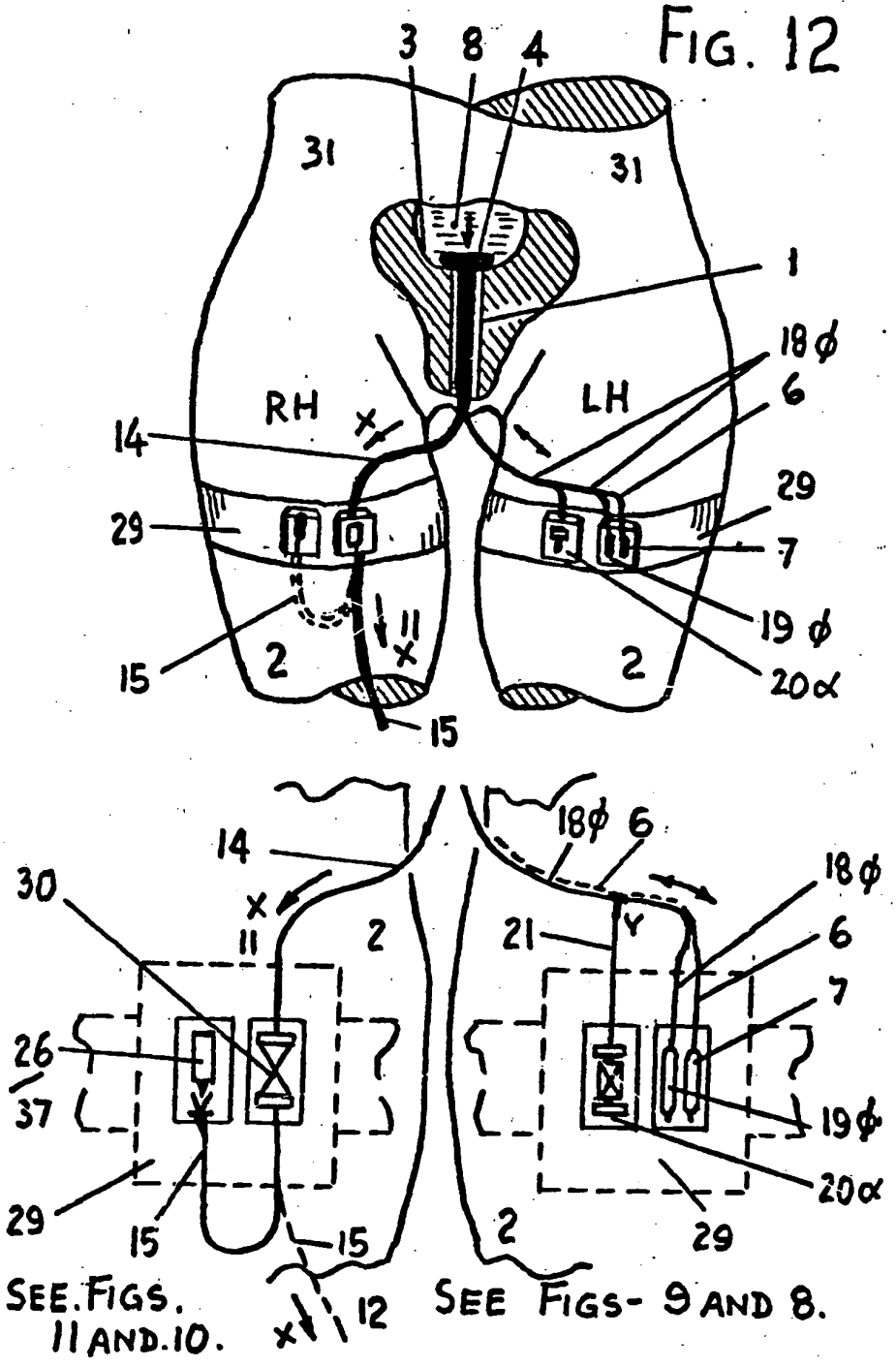


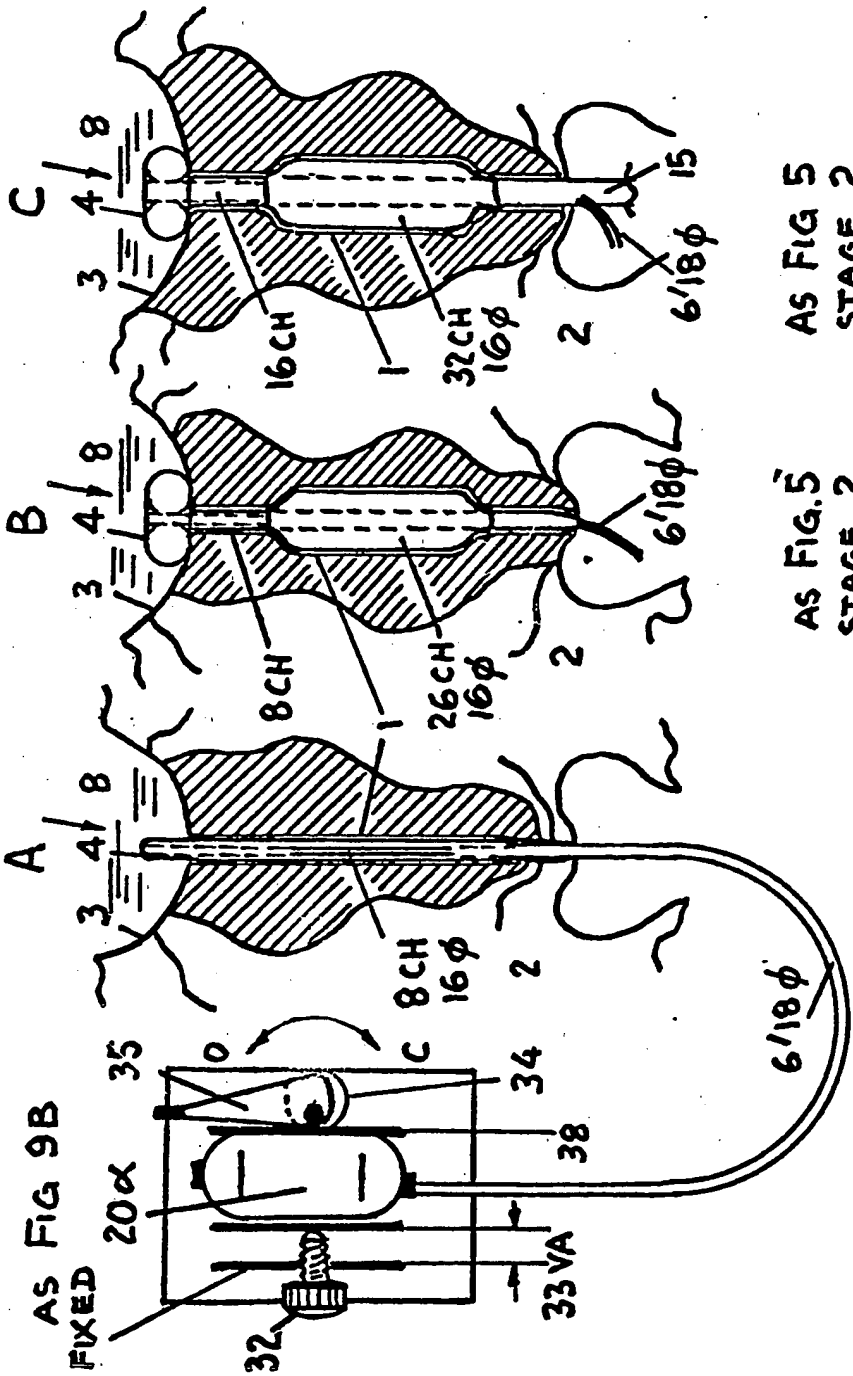
FIG. 12




SEE. FIGS. 11 AND. 10.

SEE FIGS- 9 AND 8.

FIG 13




FEMALE CATHETER - ACTUAL SIZE.

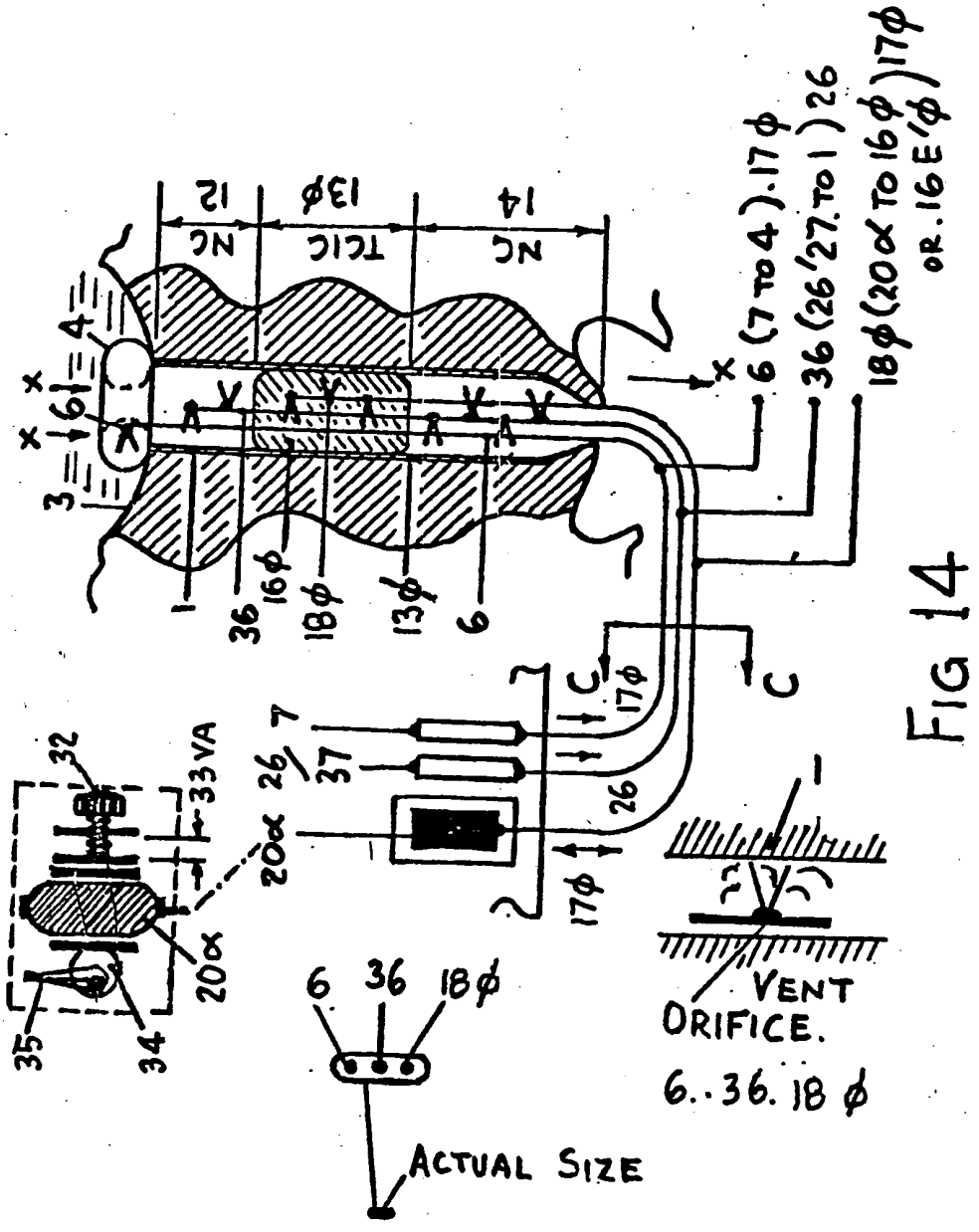



FIG 14

SECTION CC

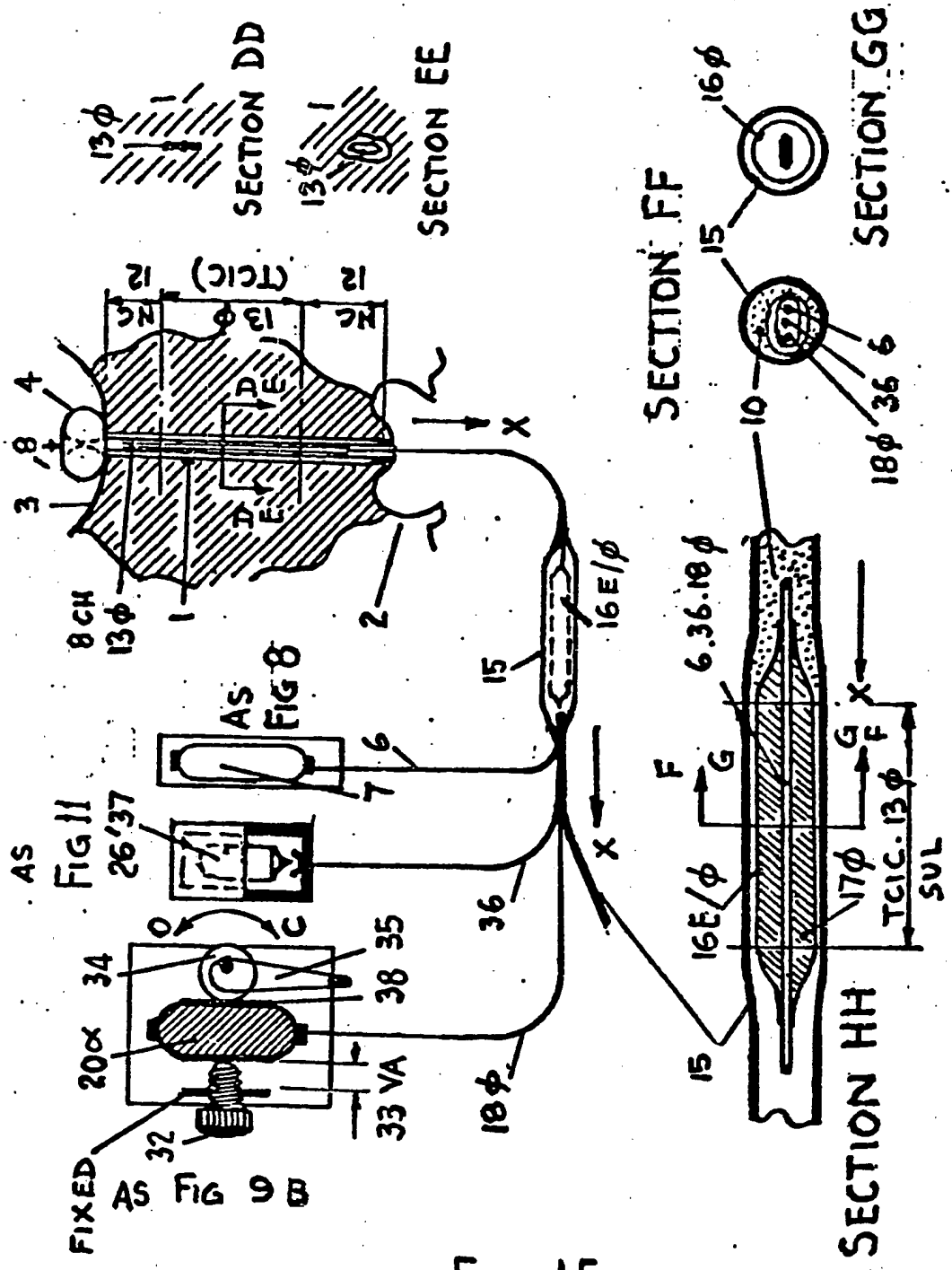
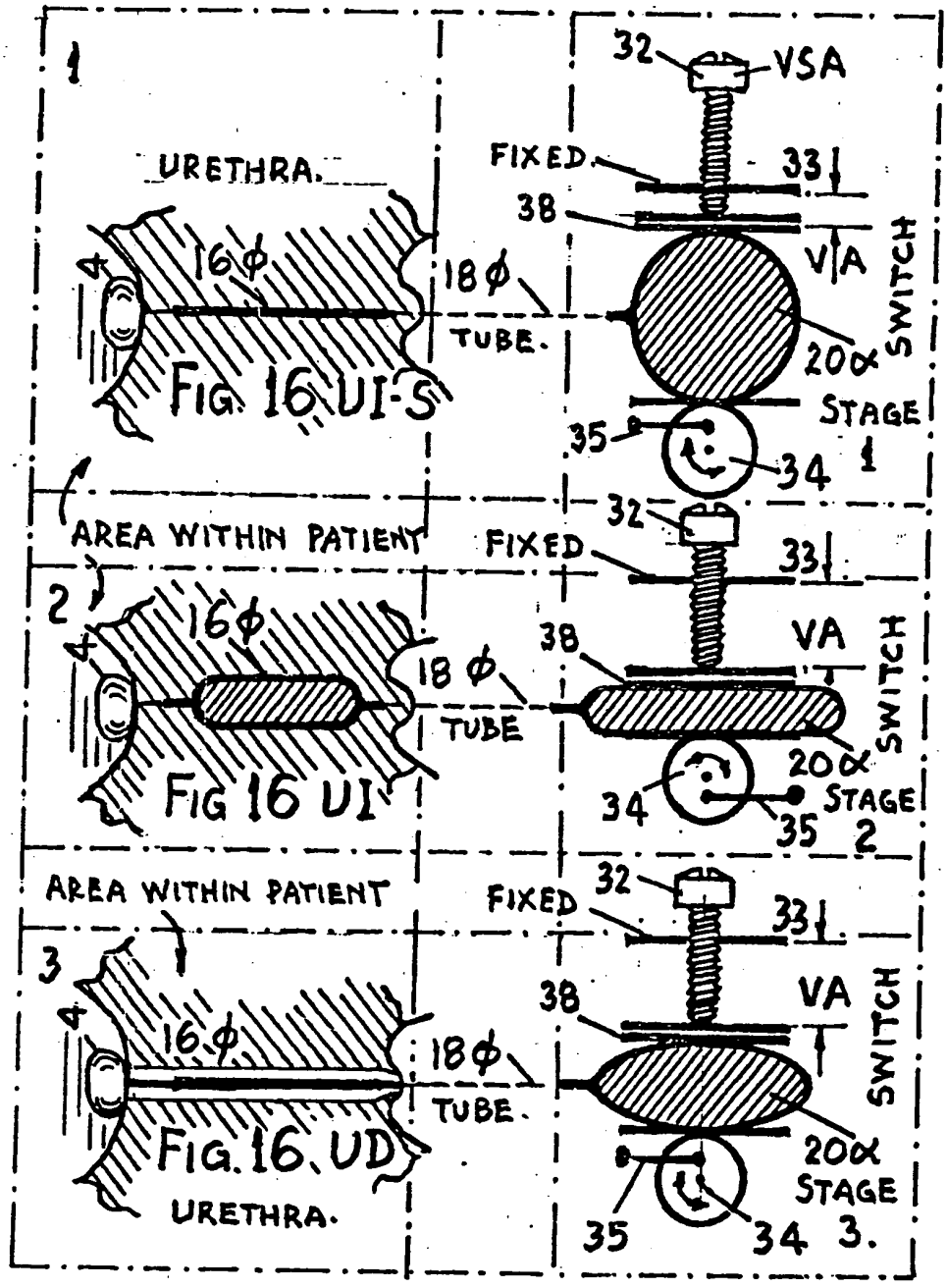

SECTION DD
SECTION EE
SECTION FF
SECTION GG
SECTION HH
AS FIG 8
AS FIG 11
FIXED AS FIG 9B
8 CH 13φ
TCIC
16E/φ
6.36.18φ
17φ
TCIC. 13φ SUL
18φ
33 VA
20α
26'37
34
35
38
36
16φ
18φ 36 6

FIG 15


1
URETHRA.
16φ
18φ
TUBE.
4
FIG. 16 UI-S
32
VSA
FIXED
33
38
VA
SWITCH
20α
STAGE
35
34
1
AREA WITHIN PATIENT
2
16φ
18φ
TUBE
FIG 16 UI
32
FIXED
33
38
VA
SWITCH
20α
STAGE
34
35
2
AREA WITHIN PATIENT
3
16φ
18φ
TUBE.
FIG. 16. UD
URETHRA.
32
FIXED
33
38
VA
SWITCH
20α
STAGE
35
34
3.

This invention relates to devices for controlling or mitigating the urinary incontinence of human male or female persons and which are hereinafter referred to as urinary incontinence control devices (UICD).

According to written medical statistics ten per cent of the human population 500 million suffer from temporary or permanent urinary incontinence or the inability of the human body sphincter muscles to control urination to appropriate selected times and place.

The human bladder as soon as any urine is collected within allows it to flow away past the faulty sphincter muscles to the external urethra exit where it causes considerable inconvenience.

Existing devices consist of the external attachment of large and obvious devices such as drainage bags, penis constriction straps, soaking pads, etc.

These with the exception of the penis constriction strap, are only external collectors or absorbers of urine without any form of involuntary urine flow control.

The external penis control device does control involuntary urination, and is externally released when urination is required.

It is towards the solution of this problem in a less traumatic better and more inconspicuous way that this invention is directed.

The Urinary Incontinence Flow Control Device (hereinafter

abbreviated to (U ICD) is specifically designed to retain a Male or Female patients Urine within the Bladder in its normal internal storeage space until such a time as the Patient decides to externally and manually by the external remote valve operated control to deflate the sphincter simulation muscle urethra pressure inflation balloon and void the contained Urine at the Patients chosen time and selected convenient location.

This type of (U ICD) device thus eliminating the external attachment of any ungainly and bulky Urine retaining and storage container strapped to the Patients leg with its constant attendant embarassment and worry to the Patient, and the consequent encumbrance and enforced restriction of the Patients Physical and Occupational movements and at the same time allowing the Patient with this new design of (UICD) to participate in the same normal necessary and enjoyable unemcumbered movements and activities as that of a normal Urine continent person.

In the Worlds Human Population - married sexual activities are the normal and natural functions of life which affects Male and Female mostly between the ages of twenty and forty five years old and this represents probably twenty per cent of the 500 Million suffering from incontinence. Unfortunately the present incontinence devices have to be removed and discarded for every sexual act, which is expensive and is a nuisance to those engaged in this activity.

The Urinary Control Device (UICD) is retained supported within the Urethra by means of a Bladder Balloon attached to the upper end of the Catheter and positioned within the Bladder area and inflated by means of a small externally located Gas/Liquid injection Inlet Valve passing the injected material via a small bore flexible Silicone Rubber tube internally adjacent to or within the Catheter Wall to the Balloon which is then inflated and is consequently larger than the Urethra Urine Bladder entrance where it is retained supporting the suspended (UICD)

Through the axial Centre of the Balloon is formed the Urine Voiding Orifice which is attached to the Upper End of the Urine Voiding Catheter Tube which is of normal thickness and flexibility and has a short length and which in turn is securely attached to a Thin Wall Compressible/Inflatable Flexible Catheter which is of an equal length to and adjacent to the Urethra Sphincter Muscle Control Area.

In turn the extreme end of the Thin Wall section is attached to the final section of the Catheter which is of a similar wall section and flexibility as the tip end of the Catheter. The length of the Catheter is related to the Patients requirements.

A Mobile Patient who can attend to his/her self would probably and usually have a shorter length of Catheter terminating just inside the Urethra exit.

An Immobile Patient would need generally a longer Catheter if the attention of a Nurse is required for Urination assistance purposes and until attention was available a temporary Urine Storeage Container could be attached to Void Urine until the Nurses assistance became available.

Three small bore flexible Silicone Rubber Tubes enter the Urethra Area within the cross section of the internal section of the Catheter. One has already previously been described for inflating the device support Bladder Balloon. The Second is a tube which is perforated in the selected suitable positions excluding the Sphincter Simulation Urethra Muscle Pressure Inflation Balloon hereinafter abbreviated to Sphincter Urethra Balloon which is a sealed unit.

This Second Tube is connected to an External Anti Biotic Gas/Liquid Aerosol Container which when needed (1) After every Urination by the Patient and/or (2) An inflamed Urethra requiring timed injections as directed by the Nurse, is used to inject Anti Biotic Gas/Fluid means within the interior of the Urethra and/or through the small bore tube wall.

The top end of this Second Tube if it is considered beneficial and useful can be extended long enough to enter the Bladder area in close proximity to the Urethra Urine voiding entrance sufficiently to inject a small amount of the Anti Biotic material directly into the Bladder every time the Urethra

is spray injected.

The Third Tube is also the same small bore diameter and material as the other two tubes but the tube wall is only pierce perforated with vent holes within the sealed Urethra Sphincter Pressure Control Balloon.

This Third Tube is also directly connected to the external Patient Manual Control Switch Gas/Liquid Reservoir Balloon with its dual switch action Voluntary Urine Voiding On/Off Cam Balloon Lever Switch and the Vernier Infinitely Variable Urethra Pressure Switch which is able to control Involuntary Urine Voiding from NIL Pressure to Urine Full Bladder Voiding Pressure and once Preset holds this setting for repeat Urination Control.

Neither of the switch control setting operations affecting the Preset Pressure adjustment setting and subsequent repeat action of the other. Within the external Gas/Liquid Reservoir Balloon Patient Manual On/Off Switch Control Unit is located an Electronic Pressure Sensor which has when being used the appropriate external Electronic Measuring and Data Recording Instruments connected to it so that the Nurse can obtain instant readings, or also at a remote desk panel in the Ward if required.

These readings can be recorded for Medical Data 24 Hours a day as required and used subsequently for reference and

Statistical purposes appertaining to the medical problem of Urinary Incontinence and also in collaboration with the medical authorities in other countries and places for comparison, rehabilitation trials and research purposes

# LIST OF COMPONENTS AND DETAILS

| NO | DESCRIPTION | SHEWN IN FIGS |
|---|---|---|
| 1 | Urethra | 1.2.4.5.6.7.9A 9B.12.13.14.15. |
| 2 | Thigh Position | 1.12.13.15 |
| 3 | Bladder | 1.12.13.14.15 |
| 4 | Balloon In Bladder (5.6.7.17) | 1.12.13.14.15 |
| 5 | Balloon Gas or Liquid Filled (4.6.7.17.) | 1. |
| 6 | Balloon -(Bladder.) Inflator Tube. or Orifice (See 4.5.7.17.) | 1.2.3.4.5.6.15 7.8.12.13.14. |
| 7 | Balloon -(Bladder) Gas Liquid Capsule (5.6) | 8.12.14.15 |
| 8 | Urine Within Bladder | 1.12.13.15 |
| 9 | Urine Within Urethra | 1. |
| 10 | Urine Flow Within Urethra Catheter → X | 1.2.6.7.9B.15. |
| 11 | Urine Flow Within External Catheter → X | 1.3.10A.10B. 12 |
| 12 | (NC) Normal Catheter Wall Thickness - Inserted Into Neck Of Urethra - Bladder End | 1.14.15 |
| 13ϕ | (TCIC) Thin Collapsible Inflatable Catheter - Urethra Sphincter Wall Contact | 1.2.4.5.6 14.15. |
| 14 | (NC) Normal Catheter Wall Thickness - Inserted Into Urethra Urine Exit End (15.) | 1.12. |
| 15 | Catheter Normal Wall Thickness External To Urethra (See Also 14.) | 1.3.7.10A.10B. 11.12.13.15. |

LIST OF COMPONENTS AND DETAILS

| NO | DESCRIPTION | SHOWN IN FIGS |
|---|---|---|
| 16 ϕ | Sphincter Simulation Muscle Urethra Pressure Inflation Balloon (See. 20.) | 1.2.4.5.6.7. 9A.9B.13.15 |
| 17 ϕ | Sphincter Simulation M.U.P.I. Balloon Gas/Liquid Filling (See Also 19.20 and 39) | 1.5.6.15. |
| 18 ϕ | Sphincter Simulation M.U.P. Inflation Tube or Orifice (16.17.19.20.) | 1.2.3.4.5.6. 7.8.9A.9B. 12.13.14.15 |
| 19 ϕ | Sphincter Simulation M.U.P.I. Balloon Gas/Liquid - Supply Balloon Valve Capsule (See Also 17. 19.20) | 8.9A.9B.12 |
| 20 ∝ | Sphincter Simulation M.U.P.I. External Variable Ajustment Control Gas/Liquid Inflation Balloon SBR (20)∝ (See Also 16.17.18.19.21.32.33VA ) | 9.9A.9B.12 13.14.15.16. |
| 21 | Inflation Tube Or Orifice Flexible Connection For Y Junction To(18)Linking (16.19.20 ·) | 8.9A.9B.12 |
| 22 | (CB) Container Box For (20) | 9 |
| 23 | (CB) Container Box For Gas/Liquid Supply Balloon Capsules (7) AND (19) Entry | 8 |

LIST OF COMPONENTS AND DETAILS

| NO | DESCRIPTION | SHEWN IN FIGS |
|---|---|---|
| 24 | (CB) Container Box For Anti-Biotic Gas/ Liquid Aerosol Container (26) | 11 |
| 25 | (CB) Container Box For Urine On/Off Urine Voiding Flow Control - Connected to (15) Catheter Ends | 10A |
| 26 | Gas/Liquid - Aerosol Container With Anti-Biotic Contents (See Also 27.28.36 and 37.) | 11.12.14.15. |
| 27 | Male Luer Aerosol Pressure Unit For Linking To Female Luer (28) From Aerosol (26) | 11 |
| 28 | Catheter (15) Urine Voiding Exit Terminal With Female Luer End To Plug Into (27) and (26) During Urine Non Voiding Intervals | 11 |
| 29 | Thigh Retaining Velcro Pads For Container Boxes And Contents (22.23.24. and 25) | 8.9.10A. 11.12 |
| 30 | Urine Voiding On/Off Control Valve - Connected Catheter Ends (15) | 10A.10B.12 |
| 31 | Female Body | 1.12 |
| 32 | Sphincter Simulation MUPI Vernier Adjustment Screw (See. 33 VA.) | 9A.9B.13. 15.16. |

LIST OF COMPONENTS AND DETAILS

| NO | DESCRIPTION | SHEWN IN FIGS |
|---|---|---|
| 33 VA | (VA) Vernier Adjustment - Preset Sphincter Simulation Muscle Urethra Pressure - Urine Flow Control - Nil to Full Bladder (See Also 16.17.18.19.20.21.32.) | 9A.9B.13 15.16. |
| 34. | Sphincter Simulation MUPI Urine Voiding Flow Control (See 20 And 35) | 9A.9B.13.16. |
| 35. | Sphincter Simulation Urethra Muscle Pressure Reservoir Balloon (20)α Volume Urine Voiding Flow - On/Off Control Lever (See 16.18.34.35.) | 9A.9B.13 15.16. |
| 36. | Urethra - Anti - Bacterial Agent Gas/Liquid Spray Inlet Tube Fig. 14 (See 26) | 2.3.4.5.6.7 9A.9B.14.15. |
| 37. | Urethra - Anti - Bacterial Gas/Liquid Supply Pressurised Capsule to (36) and To Urethra Fig. 1 (1) ABC (37) See Also(26) | 11.12.14.15 |
| 38. | Electronic Pressure Sensor | 13.15.16. |
| | | |
| | | |

LIST OF FIGURES

All Component Numbers referred to in the following figures and as previously listed in Detail and Numbered have been abbreviated to simplify the following description of the Numbered Figures as follows:

| ITEM NO. | DESCRIPTION AND ABBREVIATION | ABBREVIATION |
|---|---|---|
| 6<br>Figs 1.2.3.<br>4.5.6.7.8.12.<br>13.14 15 | Bladder Catheter Inflation Retaining Balloon Gas/Liquid Inflation Tube in Orifice (6) (See also . 4.5.7.17 .) | Bladder<br>BIT (6) |
| 16 $\phi$ .<br>Figs.1.2.<br>4.5.6.7<br>9A.9B.13 . | Sphincter Simulation Muscle Urethra Pressure Inflation Balloon as in Fig. 1 (TCIC) $\phi$ 13 (See.also . 17.18.20 ) | Sphincter<br>Balloon (16) $\phi$ |
| 18 $\phi$ FIG<br>1.2.3.4.5.6.7.<br>8.9A.9B.12.13<br>14.15 . | Sphincter Balloon (16) $\phi$<br>Gas/Liquid Inflation Tube or Orifice (See also. 13.17. 20.) | Bladder<br>BIT (18) $\phi$ |
| 20 $\alpha$<br>Figs.<br>9.9A.9B.<br>12.13.14 15 | Sphincter Simulation Balloon (16) $\phi$ External Variable Pressure (33) VA Adjustment Gas/Liquid Reservoir Capsule for for (16) $\phi$ - via (18) $\phi$<br>(See also . 16.17.18.20.) | Sphincter<br>Balloon<br>Reservoir<br>SBR (20) $\alpha$ |

LIST OF FIGURES

| ITEM NO. | DESCRIPTION AND ABBREVIATION | ABBREVIATION |
|---|---|---|
| 32<br>Fig. 9A.<br>9B.13.15.16 | Sphincter Simulation Balloon<br>(16) $\phi$ Vernier Pressure<br>Adjustment Screw (16.17.18.20) | Vernier Screw<br>VPA-S (32) |
| 33. VA<br>Fig.<br>9A.9B.<br>13.15.16. | Vernier Pressure Adjustment<br>Screw (32) for Sphincter<br>Simulation Balloon (16) $\phi$<br>to Control Urine Flow from (Nil-<br>To Full Bladder Pressure Flow) by<br>Screw Movement (See.16.17.18.20.) | Vernier Pressure<br>VPA-S.(33)VA. |
| 35<br>Fig. 9A.<br>9B.13.15<br>16. | Sphincter Simulation<br>Balloon (16) $\phi$ SBR (20) $\phi$<br>Pressure Control from Nil Flow<br>(Off) to Urine Voiding Full Flow<br>(On) Patient Voluntary Voiding<br>Reservoir Supply Control Lever (34) | Sphincter Switch<br>SB.ON/OFF. L.<br>(35) |
| 36. FIG<br>2.3.4.5.6.7.<br>9A.9B.14.15 | Urethra Anti-Bacterial<br>Agent Gas/Liquid Spray Inlet<br>Tube Fig.14 (36).(See. 26.27.) | Urethra<br>(ABT.)(36) |
| 37<br>Fig.<br>11.12.14.15 | Urethra - Anti-Bacterial<br>Gas/Liquid Supply<br>Pressurised Capsule to (36) and to<br>Urethra Fig. 1 (1) see also Fig. 11<br>(26) & Fig. 14 (37)(See 27) | Urethra Supply<br>Capsule<br>(ABC)(26/37) |

LIST OF FIGURES

| ITEM NO. | DESCRIPTION AND ABBREVIATION | ABBREVIATION |
|---|---|---|
| 38. FIG 13.15.16. | Electronic Pressure Sensor | EPS.(38) |
| | | |
| | | |
| | | |
| | | |

LIST OF FIGURES

Fig. 1 Shews a complete longitudinal axis sectional plan of the Urinary Incontinence Control Device within the Urethra and component numbers detailed with the Sphincter Simulation Urethra Muscle Pressure Balloon (16)$\phi$ within the coincident relative Urethra Sphincter Control Section shewn (TCIC) (13)$\phi$ with all the associated components applicable and detailed within the Urethra, and the sections in close proximity to the external exit of the Urethra.

Fig. 2. (Section (AA)) Shews a Cross Section taken through the Section of Fig. 1 (TCIC)(13)$\phi$ and the Sphincter Simulation Balloon (16)$\phi$ shewn fully collapsed to its minimum Charriere Size with Urine Voiding in Full Flow (10)

Fig. 3 (Section BB) Shews a Cross Section taken through the External Catheter (14) adjacent to the Urethra Urine Voiding Exit at the position detailed and indicated in Fig. 1 (Section BB) shewn Urine Voiding in Full Flow and within Catheter Wall (15)

Fig. 4 (Stage 1) Shews a cross section taken through a fully deflated Catheter Tube (13) and Sphincter Balloon (16)$\phi$ as initially installed within the Patients Urethra and not yet Preset Balloon Inflated ready for Urine Flow Control action.

LIST OF FIGURES

Fig. 5 (Stage 2) Shews the same cross section and numbered components as in Fig. 4 (Stage 1) as at and within Urethra Area (TCIC)(13)ϕ Fig. 1 but with Sphincter Balloon (16)ϕ slightly inflated controlling the Involuntary Flow of Urine at a Preset Vernier Controlled Pressure (VPAS)(33)(VA) as shewn in Fig. 9A

Fig. 6 (Stage 3) Shews the same cross section from the same Urethra Location (TCIC)(13)ϕ as in Figs. 2.4.and 5. but with the Sphincter Balloon (16)ϕ fully deflated and allowing Voluntary Patient external switch controlled Full Flow Urination.

Fig. 7 (Stage 4) Shews a cross section taken through the Catheter as shewn in Fig. 15 External to the Patients Urethra as in Fig. 1 but with the same operational components and functions as the control device in Fig. 1 as an alternative location.

This cross section illustrates the Sphincter Balloon (16 E)ϕ fully inflated within the Flexible but not deflatable Catheter(15) with the Voluntary external switch controlled by the Patient to allow full Flow Urination.

Fig. 8 and 9 Shews Gas/Fluid Inlet Valve Capsule (7) side by side with the Gas/Fluid Inlet Valve Capsule (19)ϕ

The Latter connected by Inflator Tube (18)ϕ(21) to Fig. 9. Gas/Liquid Reservoir Balloon (20)∝ as a separate item.

NOTE: Items (19)ϕ and (20)∝ would be preferably combined as one

LIST OF FIGURES

Fig. 8 and 9 cont.

integral unit (20)∝

Fig. 9A The Sphincter Pressure Balloon (16)ϕ within the Urethra (1) is Fully Inflated Preventing the Flow of Urine through the Urethra and in turn (16)ϕ is connected via Inflator Tube (18)ϕ to the Gas/Liquid Reservoir Balloon (20)∝ Switch Controlled by means of Cam (34) attached to the Control (On/Off) Switch (35) shewn with the Reservoir (20)∝ Deflated having transferred part of the Controlled Gas/Liquid Contents via (18)ϕ to (16)ϕ to inflate it to the Pressure required to control Involuntary Urination.

Fig. 9B Shews the same components as Fig. 9A operating in exactly the same way except the Cam (34) is reversed by means of lever (35) allowing the Reservoir Balloon (20)∝ to reinflate, transferring the Gas/Liquid Inflating contents from Sphincter Balloon (16)ϕ back to Balloon (20)∝

Thus deflating (16)ϕ and allowing Voluntary Urination by the Patient. Voluntary Urination by the Patient being simply effected by the Patient moving Switch Lever (35) as shewn at 20(9B) inflating (20)∝ linked to and Deflating (16)ϕ

To close the Urethra by Inflating (16)ϕ simply reverse lever (35) and Cam relative Position (34) The measured Gas/Liquid contained and sealed within Components (16)ϕ (18)ϕ and (20)∝

LIST OF FIGURES

Fig. 9B Cont.

merely being partly transferred and reversed by the Cam/Switch externally by the Patient to Urinate or not as required.

Figs. 9A & 9B Is shewn the Vernier Preset Screw Adjustment (32) required for accurate adjustment of the Spincter Balloon (16)ϕ to prevent Involuntary Drip Urination.

This remains adjusted until there is a Patient Variation in the flow rate of Involuntary Urination when it is readjusted and Preset. The set Vernier pressure control then remains the same, dependant upon the Patients future alteration and variation requirements.

There are two separate Switch functions in this Control also shewn in Fig. 15 as (9B)

(a) Voluntary Voiding Urine (On/Off) Manual Patient Control externally (34) (35)

(b) Preset Sphincter Pressure Balloon (16)ϕ for Involuntary Urethra Urine Control from Vernier Switch (32)(33)(VA)

(NIL) Drip to Full Voiding Pressure Control for a Patients Full Bladder

(VA) Variable Adjustment

Also shewn in Figs. 9A & 9B is a Cross Section CC of the small bore flexible plastic tubing for the Gas/Liquid Balloon Inflating Tubes (6) and (18)ϕ and also actual section size and additionally with a triple tube Cross Section shewn (6) (36) (18)ϕ Component (36)

LIST OF FIGURES

Fig. 9B Cont.

being used for the Urethra Internal Anti/Biotic Spray from (26)(27) Fig. 11 to the Interior of the Urethra.

Shewn also is a small Electronic Pressure Sensor (38) sandwiched between Reservoir Balloon (26) and the Pressure Adjustment Cam (34) This when installed onto and within the complete Urinary Control Device is only connected by the Nurse to a separate Electronic Digital and Tape Readout Instrument when required for additional information. It can be used for various purposes to record continuously on Tape to the Nurse directly when with the Patient or at a remote Ward Desk. The Urethra Pressure/Urethra Diameter/Catheter Diameter/Urine Flow(On/Off)/Time Flow Rate/and Quantity of Urine Voided giving statistics for every Patient in a Ward (24) Hrs./Day on a continuous tape for Doctor inspection and permanent medical records.

Figs. 10A Shew an On/Off Urine Voiding Flow Control Valve (30) connected onto the external Urine Exit Catheter (15) to Control Voiding Urine Flow and is adjusted by the Patient or Nurse as required, or alternatively if an external Catheter is not being used by a Mobile Patient can be eliminated.

Fig. 10B shews the same switch as in Fig. 10A Side View but fitted externally to the Catheter (15) with switch lever in the

LIST OF FIGURES

Fig. 10B cont.

(S) Position Urine Flow stopped and (O) Position Urine Flow Open in the direction shewn (11)

Fig. 11 Shews the External Catheter (15) exit Female Luer Tube (28) plugged onto a pressurised Anti-Bacterial Aerosol (26)(27) when not Urinating, so as to maintain an Anti-Bacterial injection material within the Catheter Urine exit tip (15) (28) at all times.

For Urination Female Luer Tip (28) and Catheter (15) are removed from Male Luer Nozzle (27) as needed by the Patient for the duration of Urination only.

Fig. 12 Shews diagrammatically located in and on the exterior of a Female Body, in the connected related operational positions all those items previously described and illustrated in Figs. (1 to 11)

Fig. 13 Shews Diagrammatically at (A) a Fully voiding Sphincter Balloon Size (8) Charriere Urinary Incontinence Control Device (16)ϕ connected by Inflation Tubes (6) (18)ϕ to the External Remote Switch Control Device as Fig. 9B Reservoir Gas/Liquid Balloon (20)∝ in the Inflated Condition with Voluntary Urination Control Switch (34)(35) in the (O) Open Voiding Position and Reversal of this Voluntary Urine Voiding Control Switch (34)(35) will Deflate Balloon (20)∝

LIST OF FIGURES

to (C) Closed and Inflate Sphincter Pressure Control Balloon (16)ϕ thus preventing Urination.

Also shewn in Fig. 13 for Comparison at (B) a (16)ϕ Charriere Sphincter Pressure Balloon (16)ϕ as Fig. 5 (Stage 2) and at (C) a (32) Charriere Sphincter Pressure Balloon (16)ϕ as Fig. 5 (Stage 2)

Fig. 14 Shews a diagrammatic section of a Urethra with a Simulated Inflator Tube arrangement within. This shews three parallel flexible small bore Inflation Tubes described as (6) Bladder Balloon Inflator Tube connected to Injection Gas/Liquid Valve Capsule (7) and the other extremity end of the tube terminating with one small vent hole for injecting Gas/Liquid directly into Bladder Balloon (4)

(18)ϕ Sphincter Inflation Tube for injecting Gas/Liquid material via pierced vent holes in its wall directly into the completely enclosed and sealed Sphincter Balloon (16)ϕ and is externally manually operated by the Nurse and/or Patient from the Gas/Liquid Reservoir Switch Control Balloon (20)ϕ attached to (18)ϕ

(36) Shews the Anti Biotic Material Flow Tube (36) connected from the external Gas/Liquid Aerosol Capsule (26)(27) to the tube internally within the Urethra and terminating within the Bladder (3) Balloon (4) Proximity. This Tube has pierced within its wall vent holes which are all located within the Urethra omitting Sphincter Balloon (16)ϕ area and with one hole in its end Bladder Tip (3) to inject Anti-Biotic Material automatically

LIST OF FIGURES

Fig. 14 Cont.

with Voluntary Urination and/or if the Urethra/Bladder are inflamed as often as necessary to kill the inflammation bacteria within the appropriate areas where needed.

Section CC Shews a section of an extruded triple small bore orifice flexible plastic inflation tube with component parallel track orifices (18)ϕ(36) (6) and also the actual size approximately (1mm X 3mm)

Fig. 15 Shews a longitudinal section of a completely Inflated Urinary Incontinence Control Device equivalent to size(8)Charriere within the Urethra as also in section shewn at Fig. 4(Stage 1)

Also shewn are sections:

(DD)Sphincter Balloon (16)ϕ and Urethra completely deflated and compressed and at(EE)more openly shewing Catheter (13) within Urethra (1.)

Catheter (15) is shewn extended as per Figs. 10A/10B/11 on the end of the External Urinary Incontinence Device remote from the Urethra.

Also shewn connected entering and sealed to the wall of Catheter (15) on the Urine Voiding End Remote to the Urethra are the three inflation tubes and controls as described in Fig.14

The external alternative Urinary Incontinence Device within Catheter Tube (15) is identical in its components and operational functions to the(UICD)incorporated within the Urethra.

LIST OF FIGURES

Fig. 15 Cont.

(Section FF) Shews a cross section of the External Urinary Incontinence Device Voiding Urine.

(Section GG) Shews a cross section of the External Urinary Incontinence Device remote from the Urethra with the Sphincter Bladder Inflated and Non Voiding Urine.

(Section (HH) Shews a longitudinal Side Sectional View of the Urinary Incontinence Control Device with the Sphincter Control Balloon inflated Non-Voiding Urine (16E)ϕ

Fig. 16 UIS UI UD

These Figures shew diagrammatically three Stages of the External Gas/Liquid Reservoir Balloon Dual Pressure Switch Control Unit connected via a small diameter flexible Rubber Tube to the Urethra Sphincter Simulation Pressure Balloon within the Urethra situ.

Fig. 16 UIS

Shews the three units connected as installed in a Patient but not yet adjusted ready for Use.

Fig. 16 UI

Shews the same three units adjusted by means of the position of the Cam and Cam Lever and also the Vernier Adjustment Screw with the Sphincter Simulation Pressure Balloon fully inflated within the Urethra preventing Urination.

Fig. 16 UD

Shews the same three Units readjusted to allow Urination by means of repositioning the Cam and Cam Lever (180°) Rotation and removing its contact pressure upon the Reservoir Balloon which then allows the empty cavity to refill with the Gas/Liquid Media Inflating Contents from the Sphincter Simulation Pressure Balloon allowing Urination to take place.

Fig. 16 UD cont.

When Urination is completed reversal of the Cam/Cam Lever Switch will return the Controls to the Non Urinating position ready for the next cycle

LIST OF FIGURES

Fig. 1.

Shews a complete longitudinal axis section Plan of the complete Catheter Involuntary Urine Voiding Control Device within the Urethra in its designed operational position in close surface contact with the portion of the Urethra shewn at (TCIC)(13)$\phi$ and the Urethra Sphincter Muscle Urine Voiding Control Section (16)$\phi$ It also shews it protruding via the Urethra exit and its immediate external connections.

The Urethra Control section of the device shown illustrates the inflated Bladder Balloon (4) with its inflationery Gas/Liquid Contents (5) supporting the retention of the Patients Catheter during its life use in the Patient.

Item (4) has an open hole in its axial centre through which the Voiding Urine passes and is connected to a short supporting length of normal Catheter Section Flexible Tube shewn in the diagram area as (NC)(12) this in turn has securely attached to it a Thin Wall Collapsible Inflatable Catheter (TCIC)(13)$\phi$ which is located in the Contact position of the Urethra in which the Urine Voiding Control of the Urethra is to be effective.

In turn on its other end is connected another portion of the Normal Catheter Tube denoted by (NC)(12) which protrudes through the Urethra Exit orifice (1) to the external portion of the

LIST OF FIGURES

Fig. 1. Cont.

Catheter (14) to which is connected all the external items required for operation of the Urethra Catheter Internally.

Through the Catheter external wall in close proximity to the Urethra is shewn the entry of the Gas/Liquid Small Bore Flexible Inflator Tubes (6) (18)ϕ and (36)

Item (6) is directly connected to Item (4) which is Inflated or Deflated by means of one small hole in its wall-Internally within Item (4)

Item (18)ϕ is also a small bore Gas/Liquid Inflation Tube which is securely anchor attached in two places external to the Sphincter Simulation Urethra Muscle Pressure Inflation Balloon (16) ϕ to the Catheter Ends (NC)(12)

The Top end of Tube (18)ϕ is blanked off, and the portion of the Tube sealed into and on each end contained within the Sphincter Balloon (16) ϕ has several pierced holes in its wall to allow Gas/Liquid Material to be injected from the External Sphincter Balloon Reservoir (20) ϕ into Sphincter Balloon (16) ϕ to effect Control of Pressure upon the Urethra Wall(1) by Inflating or Deflating the Inflation Balloon (16) ϕ as required.

LIST OF FIGURES

Fig. 1. Cont.

This is effected by Switch Pressure (34) Figs 9A.9B. upon the Reservoir Balloon (20) $\phi$ transferring Gas/Liquid as required from (20) $\phi$ Figs. 9A.9B to (16) $\phi$ and Vice Versa as needed by the Patient or Nurse to Voluntary Void the accumulated Urine contents of the Patients Bladder.

For operation of the external On/Off Urine Voiding Manual Control Unit and its relationship to Fig.(1.) see Fig.(9A) Closed/Non Voiding Control and Fig. 9B.

Open/Urine Full Voiding Flow Control which shews the method used to Control the Urethra Sphincter Area (TCIC)(13)$\phi$ by means of On/Off Switch Control (34)(35) and the Infinitely Variable Urethra Pressure Preset Screw (32)(33)(VA.)

See also Fig.(15)which shews another small bore Gas/Liquid Flexible Tube (36) which has a number of Venting Holes pierced through its Wall within the Urethra Area but not within the Sphincter Balloon (16) $\phi$ the purpose being to inject after each Urination a small dose of Anti-Bacterial Fluid onto and into the Interior of the Thin Wall Catheter (TCIC)(13)$\phi$ and onto the Urethra Wall (1.)

With a Mobile Patient the Catheter Wall may be terminated within the lower end of the Urethra and with an Immobile Patient it would be extended to allow the Nurse to Control the Patient and direct the process of Urination

LIST OF FIGURES

Fig. 1. Cont.

In all cases the three Gas/Liquid supply tubes (6)(18) and (36) would be necessary within the Urethra Section of the Catheter.

Fig. 2. (Section AA)

Shews a Cross Section as in Fig. (1) Mid Position of the Urethra Section (TCIC)(13)$\phi$ with its various components.

Urethra Wall (1) Bladder Balloon Inflation Tube (6) Urine Voiding Flow (10.) Collapsible Thin Wall Catheter Tube (TCIC)(13)$\phi$. Sphincter Simulation Balloon (16)$\phi$ Sphincter Balloon Inflation Tube (18)$\phi$ and Anti-Biotic-Injection Tube (36)

The Section shews the Balloon (16)$\phi$ fully switch control deflated by means of the external On/Off Patient Operated Voluntary Urine Voiding Switch Fig.(9B.) (20)$\phi$ with Full Flow of Voiding Urine.

Fig. 3. (Section BB)

Shews a Cross Section as in Fig.(1)through a Section of the External Catheter (14) in close proximity to the Urethra Exit point with Inflation Tubes (6) (36)and (18)$\phi$ enclosed within and shewing Flow of Voiding Urine (10)

LIST OF FIGURES

Fig. 4 (Stage 1)

Shows a cross section of the Urethra with an uninflated as initially inserted fully compressed Urinary Incontience Control Device contained therein with all numbered components as described and listed before as in Figs. (1.)(2)and (3) and to operate in the same functional manner as described in Fig.(1.)

Fig. 5 (Stage 2)

Shows a Cross section of the Urethra and the Urinary Incontinence Control Device contained therein all components as numbered previously and functioning operationally in the same manner and for the same purpose and as shewn within the area in Fig.(1)(TCIC)(13)ϕ

This section shows the Sphincter Simulation Balloon (16)ϕ partially inflated with the Gas/Liquid Filling means (17)ϕ to the required Vernier Controlled Preset Inflation Pressure by the Switch Reservoir Balloon Control (20)α as shewn in Fig 9A and the Adjustment Screw (32) to the Preset related gap for this required pressure (33)(VA.)

This is adjusted to prevent the Involuntary Flow of Urine past the direct contact surfaces (16)ϕ (TCIC)(13)ϕ and the Urethra Wall (1) all shewn in a partially inflated state and related to the flow rate of Involuntary Urination.

LIST OF FIGURES

Fig. 5 (Stage 2) Cont.

NOTE particularly that the Thin Wall Catheter (TCIC) (13)ϕ partly compressed between the adjacent axially aligned surface contact walls of the Sphincter Pressure Balloon (16)ϕ and the Inner Wall of the Urether (1) restricting the full Urine Flow

Fig. 6 (Stage 3)

Shews the same cross section of the Urethra and contained Urinary Incontinence Control Device as illustrated in Figs. (2.) (4) & (5) and numbered as previously for the same functional purposes except the illustration now shews Voluntary Urination Flow effected by the full deflation of the Sphincter Pressure Balloon (16)ϕ as in Fig.(9B) (35) and the Thin Wall Catheter (TCIC)(13)ϕ and Urethra Wall (1) fully inflated with the Urine Flow as shewn by (10.)

When Urination is complete the external Reservoir Bladder (20)α by the use of the external Cam Lever (35) as in Fig.(9A) transfer pressure returns the inflation Gas/Liquid to the Sphincter Bladder (16)ϕ to reinflate and stop all Urination as preset by Vernier Adjustment Screw (32) Fig.(9)(33)(VA)

LIST OF FIGURES

Fig. 6 (Stage 3)

This operational sequence for the components manipulation is repeated at every Voluntary Urination of the Patient.

No readjustment to the Preset Vernier Pressure adjustment screw (32) Figs (9A.)(9B) is required, and is only done as and when necessary for a different pressure control as judged by the Nurse related to the Patients rate of involuntary urination.

Fig. 7 (Stage 4)

Shews the same Cross Section of the Urethra and contained Urinary Incontinence Control Device with same numbered components and functional use as referred to in Figs. (1)to(6)except the Urinary Incontinence Control Device is shewn external to the Patient within a normal wall thickness of Catheter Tube (15) which itself is not inflatable or deflatable.

The Urinary Involuntary Control Device operates in the same manner and for the same purpose as the Device shewn within the Urethra in Fig.(1)as at (TC1C)(13)$\phi$ Section AA.

This is an alternative Control location for the device and is specifically for Patients who have disturbed and inflamed Urethras and for the duration time in healing this allows the required Sphincter Balloon (16E)$\phi$ to be inflated externally without direct pressure application upon the Urethra Wall allowing the Patient

LIST OF FIGURES

Fig. 7 (Stage 4) Cont.

to maintain both Involuntary and Voluntary Control of Urination at all times.

The Bladder Balloon (4) support of the Catheter is simply attached to a Fully Compressed Thin Wall Catheter as shewn in Fig. 4 (Stage 1) which is only inflated during Voluntary Urination thus reducing Urethra Wall inflation to a minimum.

At all times with either a Urethra Control Device or External Catheter Control Device after Urination is completed the Sphincter Balloon always returns to its Preset Vernier Control Setting Fig. 9A (32) & (33)(VA) simply to control Involuntary Urination at the minimum Urethra Pressure Control setting necessary.

Fig. 8 and 9

Shews contained and clipped into Container Box (23)(CB) and attached to the exterior of the Patient by means of Thigh Retaining Velcro Pad (29) the Bladder Balloon Gas/Liquid Inlet Valve Capsule (7) which in turn is connected to Inflator Tube (6) which connects the Gas/Fluid Inflation means (5) to Bladder Balloon (4) within the Patients Bladder for Catheter Retention within the Patients Urethra Side by side with (7) is shewn a similiar Gas/Fluid Inlet Valve (19)$\phi$ which is connected by (Y) Junction in turn to the Sphincter Simulation Muscle

LIST OF FIGURES

Fig. 8 and 9 Cont.

Pressure Inflation Balloon (16)$\phi$ by Inflation Tube (18)$\phi$ and also by the other arm of the Y Connection to Inflation Tube (21) Fig.(9) which is end connected to the Sphincter Simulation Gas/Liquid Supply Pressure Reservoir (20)$\phi$ contained in Box (22) (CB) and attached to the Patients thigh by means of Retaining Pad (29) see also Fig. 9A Balloon (16)$\phi$ Inflated Non Voiding Urine,/Closed and Fig. 9B Balloon (16)$\phi$ Deflated Urethra Voiding Urine.

When the Capsule (19)$\phi$ and Gas/Fluid Reservoir (20)$\alpha$ are filled with the appropriate volume of the Pressure Control means the Units (19)$\phi$ and (20)$\alpha$ are ready to open and close the Urine Voiding control Sphincter Urethra Pressure Bladder (16)$\phi$ as shewn in Figs. (9A) and (9B.) and as.

are the Component Units for the operational sequence controls of Sphincter Simulation Urethra Pressure Balloon (16)$\phi$ and its directly interconnected communication components shown operationally and detached in Figs. (9A) and (9B.)

Figs. 9A and 9B

Show in detail the connections numbered for the same operational functions as specified previously.

Fig. 9A shews the Urethra (1) Sphincter Pressure Balloon (16)$\phi$ Dilated Preventing the Voiding of Urine and connected by

LIST OF FIGURES

Figs. 9A and 9B Cont.

Tubes (18)$\phi$ (21) to the Gas/Liquid Reservoir Container (20)$\alpha$ which is shewn Deflated by movement means of the Cam (34) and Cam Lever (35) compressing Reservoir Balloon (20)$\alpha$ thus passing part of its Contents Gas/Liquid to the Sphincter Balloon (16)$\phi$ thereby inflating same.

Fig. 9B is the reverse action of Fig. (9A) shewing the Sphincter Balloon (16)$\phi$ fully Deflated by reversal of the Gas/Liquid Inflating Material Flow and returning it to Reservoir (20)$\alpha$ shewn reinflated by its returned materials and the reverse movement of Cam (34) and Cam Lever (35) permitting Full Urine Flow.

Thus Fig. 9A shews Urine Non Voiding and (16)$\phi$ Dilated and Fig. (9B) shews Voluntary Controlled Urine Flow and (16)$\phi$ Deflated.

This operational sequence is enacted every time Voluntary Urination takes place by simply pressing Cam Lever (35) and stopping Urination by reverse pressure on Cam Lever (35.)

NOTE: To reduce the number of Patient external controls it is preferable to amalgamate item (19) into the Reservoir Balloon (20)$\alpha$ within the Container Box so they both operate for the same purpose which is to supply Gas/Liquid contents into (20)$\alpha$

LIST OF FIGURES

Figs. 9A and 9B Cont.

( Section CC )

Shew an extruded section of (1) Twin Inflator TUBES (6) and (18) $\phi$ or (2) Triple Inflator Tube which has also (6)(18) $\phi$ and added (36) the Anti Bacterial Material supply tube.

NOTE: At all times voluntary Controlled Urine Voiding can be carried out by the Patient or Nurse Moving Cam Lever (35) On/Off Switch.

Also shewn in both Figures is an Electronic Pressure Sensor (38) sandwiched between Gas/Liquid Reservoir Balloon (20)$\alpha$ and the Reservoir Plate Pressure Control Cam (34.)

This is connected to an external electronic measuring instrument to indicate externally to the Nurse accurately the pressure being applied upon the Urethra by Voiding Urine and/or Sphincter Simulation Pressure Balloon (16) $\phi$ and which in turn is also related directly to the Sphincter Pressure Balloon (16) $\phi$ Diameter and its equivalent Charriene size.

All this data can be read out within seconds or continuously monitored or an Electronic Instrument Readout Tape for any unattended Patient at any time without removing or reajustment of the Sphincter Pressure Balloon (16) $\phi$ within the Urethra.

LIST OF FIGURES

Figs. 9A and 9B Cont.

All this reference data being externally obtained at any time without wakeing or disturbing the Patient.

Fig. 10A

Shew an On/Off Urine Full Flow Urination Control Switch (30) contained within Container Box (25) and attached to the Patients Thigh by means of Velcro Pad (29)

This Switch (30) is attached externally to the External Catheter Extension Urine Voiding Tube (15) which is also shewn in Fig. (10B) with Closing Lever in the (S) Position Closed and in the Open Position (O) and Urine Direction Voiding Flow shewn (→ 11)

This is an alternative or additional Control Switch which could be used if an external Urine Storage Container was attached for an Immobile Patient when attention is not immediately available when it is required to locate the Patient in the correct place for Urination.

This switch of course could be used for any type of Catheter being used for the same purpose.

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Fig. 11

For protection against Bacterial Infection via the interior of the extended Urine Voiding Catheter a method of Anti-Bacterial Protection is illustrated in Fig.(11)shewing Gas/Liquid Aerosol Container (26)(37) and Container Box (24)(CB)- Male Luer Aerosol Spring Loaded Gas/Liquid Aerosol Nozzle (27) attached to Patients Thigh by Velcro Retaining Pad (29) Also shewn plugged onto the Male Luer Nozzle (27) is a Female Luer Nozzle (28) attached to the terminal Urine Exit end of Catheter (15)

After each Urination the Catheter (15) End and Female Luer (28) should be carefully wiped with an antiseptic tissue and then plugged onto the Male Luer (27) at the same time receiving from the Container (26) an injection of Gas/Liquid Anti-Biotic material which sterilizes the Female Luer end and also inside the end of Catheter (15.) This connection between these components should be maintained at all times during the periods of Non Urination.

For Voluntary Urination simply Unplug (27) and(28) and direct the Catheter Terminal end (28) in the correct direction inside the waste container for disposal purposes.

This sequence is repeated for every Urination by the Patient. Additionally and/or the Urine Exit end of the Catheter may have a Catheter Tube which has been suitably impregnated internally with an Anti-Bactorial Agent which slowly exudes continuously the anti-Bacteriant within the Catheter to kill any Bacteria present or additionally a small porous capsule is inserted into the Catheter

LIST OF FIGURES

Fig. 11 Cont.

Tube and retained therein impregnated with an Anti-Bacterial exudant which has an internal hole through it to allow the free passage of Voiding Urine, the Capsule being shaped like a small short open ended tube.

See also Figs. (12) & (14) Components (26) & (37) these function in the same way as Fig. 11 (26/27) except these are linked into an extruded triple Orifice sectional Tube shewn Section(CC.)

Fig. 12

Is basically as shewn in Fig.(1)except the Urinary device is not shown in detailed section, but diagrammatically laid out in its location shown on the human body with all its Urethra internal components and external control accessories for operational control in suggested body positions.

The operation of these extra items are shown previously and explained under Figs. (2) to(11.)

Items: Figs 8.9.10 & 11 are small light in weight and inconspicuous and may be all attached together as one unit and located on the abdomen, the hip or on the lower back of the User-Patient as preferred by the Patient or according to the Users Medical Condition or Location.

LIST OF FIGURES

Fig. 12

It is not shewn in this Fig.(12)but the Electronic Pressure Sensor (38) Figs. 9A. 9B can also be used to call the Nurse to attend to the Patient as he/she needs to Urinate. Particularly if the Patient is immobile and incapable on his/her own to attend to their urgent requirement.

If the Patient is confined to the Bed, and a Nurse is not available when needed the Urine Exit end of the Catheter (15) can be attached to and used with an External Urine Collection Bag to be emptied under medical conditions by the Nurse when necessary.

Even under these circumstances it is still advantageous to use this type of Urethra Sphincter Simulation Muscle Control Catheter because its physical cross section size and internal applied pressure, is always at the minimum necessary to control involuntary Urine Voiding with minimum Urethra Long Term Trauma to the Patient.

Fig. 13

Shews as at Fig.(9B)Reservoir Gas/Liquid Balloon (20)$\alpha$ with its Control Valves (32) (33)VA and (34) (35.) Attached by the two inflation tubes (6)(18)$\phi$ and connected to the internal Sphincter Simulation Muscle Urethra Inflation Balloon (16)$\phi$ at (A)shewn as inserted Uninflated at its smallest compressed Cross Sectional Diameter about(8) Charriere, at point (B) the same unit (16)$\phi$ is inflated to(26) Charriere $\pi D$ and where(D)= 8mm dia. and at Point (C)

LIST OF FIGURES

Fig. 13 Cont.

(16)$\phi$ is shewn inflated to (32) Charriere from (16) Charriere.

This shews that for most applications one size of Control Balloon Catheter encompasses the size range of (8)Ch to (30)Charriere instead of (11) different fixed non adjustable sizes of Catheters as presently used.

Also (16)$\phi$ is infinitely variable in size from (8)Ch to (32)Charriere by adjustment of Screw Valve (32)(33) VA' Fig. 9B as preset and sustained adjusted pressures from the minimum Urethra size, necessary to control the Involuntary Urine Leak on Flow up to and also for Voluntary Voiding a Full Bladder by means of Cam (34) Lever (35) as Figs. 9A. 9B.

Fig. 14

Shews as Fig. 13 Fig 9B and Fig. 11 the same unit with component numbers and functions as previously described. Except in this case is shown it includes an additional Component (37) See also Fig.(11) which is an Anti-Bacterial Gas/Liquid Supply Pressure Capsule (37) connected to Supply Tube (36) which is shown within the Urethra with pierced Vent Holes through its side for Spraying the(AB)material within the Urethra and the adjacent internal Urethra areas of the Catheter, it does not spray into the (TCIC)(13)$\phi$ Sphincter Capsule (16)$\phi$ which is entirely sealed except to Gas/Liquid Inflation Tube (18.)$\phi$

Fig. 14 Cont.

NOTE - The Anti Biotic Aerosol Capsule (37) would preferably be incorporated attached to and within part of the external manual Patient Remote external Sphincter Control Unit (20α) as in Figs. 9A and 9B such that when Cam Switch (34) is rotated positioned as in Fig. 9B with Urination shewn taking place When Voiding ceases to stop further urination the Urethra Pressure Control Balloon (16ϕ) is reinflated by rotating Cam Switch (180°) as shewn in Fig. 9A to prevent further urination and at the same time the Urethra is Automatically injected with one graduated and measured shot of Anti Bacterial Spray via the perforated Urethra Situ located spray tube (36) from the Anti Bacterial Aerosol (37) by means of a formed Cam Lobe located on/and as part of the Centre Axis of Cam Switch (34) so that as the Cam Switch is rotated (180°) to the Non Voiding Position as in Fig. 9A the Cam Lobe rotates past and pressure triggers the Aerosol Nozzle to eject one prescribed Shot of Anti Bacterial Fluid

If in Hospital Practise it is decided the Anti Biotic Spray for cost economy should be reduced the AB Switch can be modified to deliver one Anti Bacterial Shot or Spray per ever 2.3 or 4 Voiding Urinations

LIST OF FIGURES

Fig. 14 Cont.

These Tubes (18)ϕ (36)(6) can be extruded as a one piece flexible Silicone Rubber Tube shewn at Section (CC.)

Also if a Catheter Urinary Incontience Device is not being used the Components (36) and (37) can be used on their own to spray into the Urethra as required by the Nurse Anti-Bacterical or other healing materials onto an Inflamed Urethra.

The Tubes (18)ϕ(36)(6) would be encompassed and formed into the Urinary Incontinence Control Device as it was manufactured as a single assembled unit.

Fig. 15

Shews in their relative Connected positions the various components previously described in Figs. 1 to 14 with the exception that the Involuntary Urinary Control Device is shewn located external to the Urethra but within the external portion of the Catheter adjacent proximity to the Urethra.

The Device using the same Components and for the same functional use as the Urethra Located Control Device.

The Catheter Wall (15) is Silicone Rubber flexible normal thickness but not required to be dilatable.

The Sphincter Pressure Balloon (16 E)ϕ being inflated by the

LIST OF FIGURES

Fig. 15 Cont.

same control unit (20)∝ and manner as before. Section(FF)shews an extruded triple Inflation and Anti Bacterial Tube(18)ϕ(36)(6) within Balloon (16E)ϕ also shewn dotted is Urine Section (FF) Voiding and Section(GG)Non Voiding Controlled.

Shewn in the Urethra located and supported therein by Bladder Balloon (4) is a Catheter Thin Wall (TCIC) (13)ϕ Collapsed Uninflated and with a small compressed diameter about (8 to 10)Charriere as it does not contain the Sphincter Pressure Balloon (16E)ϕ

Also within the Urethra are two small diameter tubes (36) and (6) and not tube(18)ϕ as it is not required within the Urethra for Urinary Incontinence Control Purposes. With this arrangement the Patient has full external control of Involuntary and Voluntary Urine Voiding but with the external Urinary Control Device only internally Urethra suspended on the Non Inflatable Minimum Non Expandable Catheter Bladder Balloon Support which indicates that no inflation of the Urethra is caused at any time by any Balloon Pressure Inflation Non Voiding Urine adjustment externally and any internal Urethra dilution only takes place when the Patient is Voluntarily Urinating and for its duration time only. (ie: 1% of the Day)

Fig. 16 U1S

Shews a diagrammatic end view(Stage 1)of a Reservoir Gas/Liquid Supply Balloon External Switch Control Unit (20)∝ and as freshly inserted into the Patient(Area 1)and not adjusted connected via a small diameter flexible Rubber Gas/Liquid Supply Tube (18)ϕ to a Sphincter Simulator Urethra Muscle Pressure Balloon (16)ϕ within a Patients Urethra(Area 1)

On this device are two fixed position points the Fixed Screw Plate (33) and the Centre Pin Rotating Point of Cam (34) relative to the Centreline of the Balloon and at right angles to these two centres.

Fig. 16 U1

When setting the device into the Patients Urethra(Area 2) Correctly insert (16)ϕ and at(Stage 2) rotate Cam (34) and Cam Lever (35) at shewn for maximum pressure upon Reservoir Gas/Liquid Supply Balloon (RSB)(20)∝and then adjust Vernier Screw Adjustment (32) (VSA) to squeeze transfer Gas/Liquid via Tube (18)ϕ into Sphincter Urethra Inflation Balloon (16)ϕ until Patients Involuntary Urination just ceases - wait and repeat this operation until all Involuntary Urination just ceases. Stop any further adjustment of (VSA)(32) and record the dial reading and do not alter. This will need no further adjustment and only by the Nurse unless the Patients Physical Conditions change in that event readjust as necessary and record the new dial reading and do not readjust.

Fig. 16 UD

Finally the device is now adjusted in its operational situ, and if the Mobile Patient wants to Urinate at any time in the correct place he/she only has to operate (Stage 3) the Cam Lever (35) to release Cam (34) Pressure upon (RSB)(20)$\alpha$ and to withdraw Gas/Liquid from Sphincter Urethra Inflation Balloon (16)$\phi$ to restore it back again into (RSB)(20)$\alpha$ and to deflate (16)$\phi$ for Urination.

When Urination is complete the Patient only has to operate the Cam Lever (35) and Cam (34) to the (RSB)(20)$\alpha$ position as shewn in (Stage 2) to reinflate via (18)$\phi$ the Gas/Liquid Media contents return back into Sphincter Urethra Inflation Balloon (16)$\phi$ to stop any further Urination.

This rotation movement of Cam (34) and Lever (35) is the only action the Patient has to attend to every time he/she Urinates at the same time the connected (not shewn in diagrams) Anti Biotic Gas/Liquid Spray Nozzle will be tripped by the Cam Lever (35) to inject directly into the Urethra after every Urination one controlled adjusted dose of Anti Biotic fluid automatically from the attached Aerosol side by side with the

(RSB) (20)$\alpha$

Claims 1 To 7

As claimed in 1
Items referred to have their descriptions for clarity abbreviated to Symbols as detailed tabulated below-

| FULL DESCRIPTION | REF. NO. | CLAIM ABBREVIATION |
|---|---|---|
| Internal Sphincter Simulation Urethra Muscle Pressure Balloon (16)ϕ | C1 SEE. ALSO. C2. | (ISSUMPB) |
| Exterior-Alternative-(UICD) (C1)(16E)ϕ | C2 SEE. ALSO. C1. | EA (ISSUMPB) |
| Thin Wall Flexible Inflatable Internal Catheter (13)ϕ | C3 | (TWF1IC) |
| Flexible Rubber Tube (18)ϕ Small Diam. Bore (See 16.20) | C4 | (FRT) |
| Gas/Liquid Flow Media (26) (Anti-Biotic) (See 27) | C5 | (GLFM) AB |
| Manual (On/Off) Voluntary Urination Control Switch (34'35) | C6 | (MVUCS) |
| Reservoir Supply Balloon (20)α (Gas/Liquid) (See 16 17) | C7 SEE ALSO. C6 AND C9 | (RSB) |
| Cam. Lever Switch (34)(35) | C8 | (CLS) |
| Vernier Infinitely Variable Adjustable (RSB) (See 32/33VA) Repeat Pressure Switch | C9 SEE. ALSO. C7 | VIVA PRPS |

| FULL DESCRIPTION | REF. NO. | CLAIM ABBREVIATION |
|---|---|---|
| Urination On/Off Control Switch (35) (35) | C10 | (UCS) |
| Voluntary and Involuntary Urination (10) (11) | C11 | (V/IU) |
| Gas/Liquid Flow Media (Inflation) (17) (See 16 20) | C12 | (GLFM) I |
| | C13 | |
| | C14 | |
| | C15 | |
| | C16 | |

Claim 1

A completely integrated device system for Voluntary and Involuntary Urination Control by retaining the Patients Urine within the Patients Bladder until he/she needs to void in the correct place and appropriate time eliminating the necessity as at present with current existing equipment available to use attached to the Patient-external Urine Storage Bags or Containers which because of their storage capacity have to be emptied several times a day or night this device overcomes this problem by incorporating several operational functions tabulated in sequence as follows - Internal Sphincter Simulation Muscle Urethra Pressure Inflation Balloon (C1)(16)$\phi$ and additionally for use as an alternative to the preceding an external Catheter located Sphincter Simulation Muscle Urethra Pressure Inflation Balloon (C2)(16E)$\phi$ which embodies the same components as (C1)(16)$\phi$ and operates in exactly the same functional manner by means of a dual adjustable external Balloon Pressure Switch (C7)(20)$\propto$ (C6)(C9) attached to either (C1)(16)$\phi$ or (C2)(C16E)$\phi$ depending on the conditional requirements of the Patients Urethra tissue by means of the inflationary (Gas/Liquid) Flow Media (C12)(17) which is moved either to Inflate (C1)(16)$\phi$ or (C2)(16E)$\phi$ for Non Urination or Deflate (C1)(16)$\phi$ or (C2)(16E)$\phi$ for Urination with movement of this (Gas/Liquid) inflation media (C12)(17) being actuated by means of Pressure Switch Reservoir Balloon (C7)(20)$\propto$ transferring via the Small Diameter flexible

Claim 1 cont...

Rubber Tube (C4)(18)ϕ connecting either (C1)(16)ϕ or (C2)(16E)ϕ to the Involuntary Urinating Pressure Control (C7)(20)∝ being Vernier Infinitely Variably Controlled by Switch (C9)(32'33)(VA) the said Control Variation pressure adjustable from Zero (Drip) to Maximum Full Bladder Urine Flow Control once the Vernier Switch (C9)(32'33)(VA) has been adjusted and set only by the Nurse it remains at this setting unless the Patients Body Conditions warrants any slight readjustment and when the Patient requires to Voluntarily Urinate (he/she) actuates the other external Cam Lever Switch (C8)(34'35) which in one position allows the Reservoir Balloon (C7)(20)∝ to Inflate withdrawing the Pressure Inflation (Gas/Liquid) media (C12)(17) from (C1)(16)ϕ or (C2)(16E)ϕ thus allowing full flow Voluntary Urination to take place and by rotating or switching the Cam Lever Switch (C8)(34'35) to the (Off) or Reverse position will return the balloon media (C12)(37) contents from (C7)(20)∝ previously obtained from (C1)(16)ϕ or (C2)(16E)ϕ Reinflating either to the same Internal Volume and Pressure as before thus preventing Voluntary Urination but also at the same time reinstating the Involuntary Urination Control Preadjusted Pressure (C9)(32'33)(VA) within (C1)(16)ϕ or (C2)(16E)ϕ and at the same time the Cam Lever (C8)(34'35) is switched to the Off/Non Urination position a small prescribed measured quantity or dose of Anti-Biotic Fluid (C5)(26) is injected within the Urethra and Bladder Area via a

Claim 1 cont...

Small dia. Flexible Tube (36) parallel to the other small Dia. Tube (6) and which has several staggered position small diameter holes pierced through its Wall to permit the Venting of the Anti-Biotic material (C5)(26) in the form of a spray directly internally upon the Urethra (1) Surface with the transition from Involuntary to Voluntary Urination Control requiring the Patient to simply rotate or move the Cam Lever Switch (C8)(34'35) from the On/Voiding Position to the Off/Non Voiding Urine position No other functional Operation being used or needed by the Patient and when the external Urethra Bladder Pressure Control (C2)(16E)ϕ is being used the Patients Urethra is only subject to the minimum pressure from the suspended non inflatable Catheter (13)ϕ located internally in contact with the Urethra which is a reduced section approximately ( 8 to 10) Charriere about (3 MM) diameter and at the same time the Urethra is being intermittently injected as prescribed by the Doctor via the integrally contained small dia. flexible Anti Biotic Rubber Tube (36) with the Anti Biotic Media (C5)(26) until the Urethra is healed so that the Alternative External Urethra Pressure Balloon (C2)(16E)ϕ can be removed and the usual internal Urethra Inflation Balloon (C1)(16)ϕ be installed in its place for long term Involuntary Urination Control also incorporated within the external Dual Balloon Pressure Switch Control (C6)(34'35) and (C9)(32'33)VA is located a Thin Transducer Electronic Pressure Senser (38) which

Claim 1 cont...

is sandwiched between the Reservoir Balloon (C7)(20)∝ surface and one of the Inflation Control adjustable pressure switch contact points (C6)(34/35) or (C9)(32'33)VA. this Senser enabling the Nurse to externally connect to is an Electronic Test Measuring Instrument or Device and/or have remotely located in the Ward on the Nurses Desk a Computer Multi Terminal Readout Tape which would readout and record the Urinary Statistical Information from a number of Patients at the same time which could be subsequently referred to or filed for statistical purposes the Nurses direct readout at any time even with a sleeping patient will give the Urethra/Catheter Diameters/Pressure/Urine Flow Rate/ and Pressure and the Patients Control Unit will without disturbing the Patient enable the Nurse to ascertain Urethra and Catheter Diameters/ Pressures etc and the Nurse if it is required can also operate the Patient Voluntary Urination Switch to Void the Patients Urine

Claim 2

A claim as in Claim 1

A device that has located within the Patients Urethra an Inflatable/Deflatable - Internal Sphincter Simulation Urethra Muscle Pressure Balloon (ISSUMPB)(C1)(16)$\phi$ which applies internally directly and indirectly pressure upon the Urethra Wall via a Thin Wall Flexible Inflatable Internal Catheter (TWFIIC) (C3)(13)$\phi$ within which it is located and supported to control Voluntary/and Involuntary Urination (V'IU)(C11)(10'11)

The Pressure for (C1)(16)$\phi$ being supplied via a small bore Flexible Rubber Tube (FRT)(C4)(18)$\phi$ which is attached to an external Reservoir Supply Balloon Gas/Liquid Media (RSB)(C7) (20)$\alpha$ which contains the inflationary Gas/Liquid Flow Media (GLFM)(C5) (26) and whose flow controlling (C1)(16)$\phi$ is determined by means of the external Patient Manual (On/Off) Voluntary Urination Control Switch (MVUCS)(C6)(34/35) and the Vernier Infinitely Variable Adjustable (RSB)(C7)(20)$\alpha$ Preset Repeat Pressure Switch (VIVA) (PRPS)(C9)(32'33 VA)

The Nurse presets the Vernier Control Switch (C9)(32'33)VA. at the pressure level required to stop Urination (V'IU)(C11)(10'11) which is retained and with pressure repeatable control for each subsequent urination

The adjustment of this switch (VIVA)(PRPS)(C9)(32'33)VA. is Vernier controlled by the intregal internal Switch adjusting screw to the pressure required to transfer a measured quantity of

Claim 2 cont...

Gas/Liquid Media (GFLM)(C5)(26) from (RSB)(C7)(20)α via (FRT)(C4)(18)ϕ to (ISSUMPB)(C1)(16)ϕ the Urethra Pressure Control Balloon

This Vernier Adjustable Pressure Switch (VIVA)(C9)(32'33)VA. prevents the Urethra Urination Flow to be stopped from (Nil) Drip Urine Flow to Maximum Full Bladder Urine Flow and with repeat controlability

The Patient or Nurse can effect Voluntary Urination (V/IU) (C11)(10'11) as required by external Manual operation of (MVUCS) (C6)(34'35) Switch (On/Off) as required which is the Only Operation or Action required by the Patient

All switch pressure adjustments transmitted directly (VIVA) (PRPS)(C9)(32'33)VA, internally to the Patients Urethra (1) can be externally adjusted and controlled within seconds by the Nurse without wakeing a sleeping Patient at any time or handling the Internal Sphincter Pressure Balloon (ISSUMPB)(C1)(16)ϕ.

Claim 3

A claim as in Claims 1 and 2 that has alternatively

A device that has incorporated externally within close proximity to the Urethra exterior and within the external section of the Catheter (15) emerging from the Urethra a duplicate Sphincter Simulation Urethra Muscle Pressure Urinary Incontinence Control (EA)(C2)(16E)ϕ device which is not in direct contact with the interior of the Urethra other than indirectly by the Voiding Urine but operates in exactly the same way functionally and with the same components as the Urethra Incontinence Control Device (1SSUMPB)(C1)(16)ϕ

This parallel similiar Control device's function is to control Voluntary and Involuntary Urination (V'IU)(C11)(10'11) externally without any internal direct pressure upon the Urethra and is particularly necessary when a Patient has a seriously Inflamed Tissure Urethra and cannot withstand the additional trauma caused by any extraneous direct pressure applied upon it

However the external Urination Control (EA)(C2)(16E)ϕ device needs support to retain it within and attached to the Urethra Interior which is effected by means of three components.

1 (6) A small bore flexible Rubber of Plastic Tube (1)(6) attached to a normal existing type Bladder Support (4) Balloon and inflated by the usual external means.

2 (36) A second tube (FRT)(C4)(18)ϕ attached parallel to (1)(6) which extends the whole length within the Urethra and

Claim 3 cont...

a small amount into the Bladder (3) which has perforated small Anti-Biotic Spray Media (GLFM)(C5)(26) venting holes pierced into its wall within the vicinity of the Urethra area.

5. 3. With (1)(6) and (2)(36) attached internally to a Thin Wall Flexible Collapsible Inflatable Catheter Wall (TWF11C)(C3)(13)$\phi$ which just prior to the Urethra exit is more rigidly attached to a usual flexible thicker wall section Catheter Tube (15) inside which is enclosed the alternative Urination Control Device (EA)(C2)(16E)$\phi$ as previously described.

In operation the Nurse as prescribed or specified by the Doctor directly injects from an externally attached Anti-Biotic Gas/Liquid media Aerosol (GFLM)(C5)(26) or Hypodermic Syringe via Tube (1)(6)(FRT)(C4)(18)$\phi$ the Anti-Bacterial Agent (GLFM)(C5)(26) upon the Urethra Wall at specified times until the Urethra Wall tissue heals.

The reduction in cross sectional Catheter (TWF11C)(C3)(13)$\phi$ diameter section being used in Contact with an inflamed Urethra being approximately ( 3 MM) diameter or (9) Charriere.

When appropriate the Internal Voluntary & Involuntary Urination Control Device (1SSUMPB)(C1)(16)$\phi$ can be used again should it be required by the Patient eliminating the use of the external duplicate control device (EA)(C2)(16E)$\phi$.

Claim 4

A claim as in Claims 1, 2 and 3.

A device that has an important external switch component incorporating means to Control the Voluntary Voiding of Urine (V'1U)(C11)(10'11) and also the Involuntary Voiding of Urine (V'1U)(C11)(10'11)

This external Unit is attached by means of a Flexible Rubber Tube (FRT)(C4)(18)$\phi$ to the Internal Sphincter Simulation Urethra Muscle Pressure Balloon (ISSUMPB)(C1)(16)$\phi$ which when inflated by the Gas/Liquid Flow Media (GLFM)(I)(C12)(17) injected from the Reservoir Supply Balloon (Gas/Liquid)(RSB)(C7)(20)$\alpha$ applies direct pressure upon the Urethra Wall thus impeding and stopping Voluntary and Involuntary Urination (V'1U)(C11)(10'11) and when deflated by the Patients manual operation of the Manual (On/Off) Voluntary Urination Control Switch (MVUCS)(C6)(34'35) allows Full Flow Urine Voiding to take place.

The operation of the (MVUCS)(C6)(34'35) being actuated by turning the Cam Lever Switch (CLS)(C8)(34'35) from applying pressure upon the (MVUCS)(C6)(34'35) and withdrawing (GLFM)(I)(C12)(17) directly from the (ISSUMPB)(C1)(16)$\phi$ which then allows the Full Flow of (V'1U)(C11)(10'11)

Reversal of the Cam Lever Switch (CLS)(C8)(34'35) applies pressure upon the (RSB)(C6)(20)$\alpha$ and allows the injection of (GLFM)(I)(C12)(17) to return to inflating the (ISSUMPB)(C1)(16)$\phi$ which then applies direct pressure upon the Urethra and prevents

Claim 4 cont..

(V'IU)(C11)(10'11) to take place

So the Patient to Voluntary Urinate has only to switch the Cam Lever (CLS)(C8)(34'35) to non pressure upon (RSB)(C7)(20)∝ to allow Full Flow Voluntary Urination and operation of the (CLS)(C8)(34'35) to apply pressure upon (RSB)(C7)(20)∝ prevents Urination.

This is only actuated when the Patient feels internally that the Bladder has enough contents and required to Urinate.

The operation of the second incorporated Dual Switch the Vernier Infinitely Variable Adjustable (VIVA)(PRPS)(C9)(32'33)VA preset Repeat Pressure Switch which also applies directly variable control pressure upon the Reservoir Supply Balloon (RSB)(C7)(20)∝ which is thereby adjustably compressed or decompressed by means of the Vernier threaded adjusting screw (VIVA)(PRPS)(C9)(32'33)VA twisted in a Fixed Plate Location and moving when twisted either way another pressure plate laying in contact on the (RSB)(C7)(20)∝ Surface.

So that adjustment one way releases pressure upon the (RSB)(C7)(20)∝ and causes it to withdraw (GFLM)(C12)(17) from the (ISSUMPB)(C1)(16)ϕ thus deflating it as required and reducing the Involuntary Urination application Preset Control Pressure (VIVA)(PRPS)(C9)(32'33)VA and twisting the Vernier adjusting Screw (VIVA)(PRPS)(C9)(32'33)VA the other way will apply increased pressure upon (RSB)(C7)(20)∝ which in turn will increase the inflation

Claim 4 cont...

of the (ISSUMPB)(C1)(16)$\phi$ thus increasing the Urethra Involuntary Urination Control Pressure.

Bladder (ISSUMPB)(C1)(16)$\phi$ is inflated by (C9)(C12) by the Gas/Liquid Media Transfer from (RSB)(C7)(20)$\alpha$ and with (CLS)(C8)(34'35) Cam Lever Switch at maximum preset compressing position on (RSB)(C7)(20)$\alpha$

Part (B) (WU) Patient Voluntary Urinating Sequence by Patient Manual Operation of Cam Lever Switch (CLS)(C8)(34'35)(C12)(17) Contents of Bladder (ISSUMPB)(C1)(16)$\phi$ returned to (RSB)(C7)(20)$\alpha$ by Deflating (C1)(16)$\phi$ and rotating Cam Lever Switch (CLS)(C8)(32'33)VA (180°)

Note-Do not touch or reset (C9)(32'33)VA the returned (C12)(17) will return into (RSB)(C7)(20)$\alpha$ the area controlled by (C9)(32'33)VA.

To return to the Non Voiding Urination setting Patient merely allows Cam Lever Switch (CLS)(C8)(34'35)$^{(180°)}_{\Delta}$ to full compression Position on (RSB)(C7)(20)$\alpha$ which will then return (C12)(17) to Urethra Pressure Control (C1)(16)$\phi$ or (C2)(16E)$\phi$ This sequence of Cam Lever Switch (CLS)(C8)(34'35) Movement by the Patient is all that is necessary and which is Automatic when Patient releases Switch (CLS)(C8)(34'35)

Any readjustment of (C9)(32'33)VA being done only by the Nurse or Doctor when the Patient Involuntary Urination Conditions alter.

This Urinary Incontinence Inflatable Sphincter Balloon

Claim 4 cont...

(1SSUMPB)(C1)(16)$\phi$ which is infinitely Balloon Volume and diameter adjustable from (8 to 10) Charriere to (30) Charriere size in one Catheter means that at all times the Urethra internal diameter is deflated to a minimum for (98%) of the time and only for (2%) of the time when it is only additionally dilated by means of the Urine Flow.

Unlike existing fixed diameter or Charriere Size Catheters which are a fixed rigid non adjustable Charriere Size and are dilated for Full Flow Urination (100%) of the time with the Urethra unnecessarily distended causing long term Patient Trauma.

Thus the (VIVA)(PRPS)(C9)(32'33)VA. Switch will allow the Urethra to control Urination infinitely adjustable Pressure Stepless from Minimum (NIL) Drip Flow to Full Flow Urination from a Full Bladder with one Catheter covering the whole range of Charriere sizes.

This (C9)(32'33)VA is preset to the correct control pressure by the Nurse only and is readjusted as necessary if the Patients Physical requirements justify it.

The Manual (On/Off) Switch (MVUCS)(C6)(34'35) over-rides the (C9)(32'33)VA. switch preset by the Nurse and switches off automatically when it is released by the Patient

Neither Switch operation alters the preset adjustment of the other which remains the same.

Both of these switches can be operated or readjusted by the

Claim 4 cont...

Nurse externally even if a Patient is confined to Bed and is asleep without awakening the Patient.

The Gas/Liquid Media Volume Storeage Capacity of the (RSB)(C 7)(20)α is directly related to the Maximium Charriere Size (ISSUMPB)(C1)(16)ϕ the Catheter is to be inflated to and if we designate this max. Volume Capacity of (ISSUMPB)(C1) as V(C1) then the Capacity of the (RSB)(C7)(20)α is (C9)(32'33)(VA) the Max. in Total Displacement Capacity to supply the (ISSUMPB)(C1)(16)ϕ Balloon from the storeage volume in (C7)(20)α is V(C1) and allowing an additional reserve volume of 20% (C1) or 0.2 V.(C1) then the Total Capacity of (C7)(20)α is (1.2 V)

Thus when non Urinating - Volume (V) inflating media has been transferred from (RSB)(C7)(20)α to (C1)(16)ϕ by compressing (C7)(20)α by means of (C8)(34'35) rotation leaving a balance of 0.2V media in (C7)(20)α not required.

Reversing the Cam Lever Switch (CLS)(C8)(34'35) and thus inflating Balloon (C7)(20)α will automatically return the (V) Contents of (C1)(16)ϕ back to (C7)(20)α thus dilating (C1)(16)ϕ and permitting full flow Urination.

Once (C9)(32'33)VA has been preset for the Patient it is not altered by the Nurse unless vitally necessary.

Movement of the (CLS)(C8)(34'35) is the control of the Voluntary Urination of the Patient, which is done as required and when the switch is released after Urination, shuts down the flow

Claim 4 cont...

of Urination at the same time automatically injects a regulated doseage of Anti-Biotic Fluid (GLFM)(AB)(C5)(26) into the Patients Urethra. (1) after each compleated Urination.

Not shown in the Figures (9, 9A & 9B) illustrations is a means that in the event of an Immobile Bed Patient requiring Nurse assistance and which does not come and the Bladder Contents Volume has increased unduly and requires urgently voiding, in addition to the Electronic Pressure Sensor (EPS)(38) Alarm Bells the (EPS)(38) can operate automatically by Means of a (3v.) Battery an Electro Magnet Trip Finger which will enable the spring loaded (CLS)(CB)(34/35) to return to the position enabling the (RSB)(C7)(20)$\alpha$ to deflate the (ISSUMPB)(C1)(20)$\alpha$ Balloon and Voluntarily urinate either into the Bed or onto the Floor unless the Nurse has made provision for this event to take place by attaching a Urine Storage Container previously. After Urination the Nurse would reset (C6)(34/35) to the Non Urinating off position

Operational sequence of Urination Controls (C1)(16)$\phi$ or (C2)(16E)$\phi$ -(C12)-(C7)-(C6) for (C11) Non Urination & Voluntary Ufinating Device Located in Patient Ready Operational Situ Position Part (A) (NU) Patient Non Urination Sequence.

Claim 5

A claim as in Claims 1, 2, 3 & 4 which is a device incorporating an Electronic Pressure Sensor (38) located within the Patient Manual Voluntary Urine Voiding On/Off Switch Control Unit (MVUCS)(C6)(34'35) Vernier Infinitely Variable Adjustable (RSB)(C7)(20)$\alpha$ Preset Repeat Pressure Switch Unit (VIVA)(PRPS)(C9)(32'33)$^{VA}_{A}$ and their two pressure Plates Contacts Inflatable/Deflatable Reservoir Supply Balloon (Gas/Liquid)(RSB)(C7)(20)$\alpha$ exterior surface.

Such that any pressure or variation of pressure within (C7)(20)$\alpha$ will automatically produce an Electronic signal (38) readout readily available when connected to a Nurse applied Computer or Digital Readout Multimeter which will enable the Nurse at any time without awakening a sleeping Patient ascertain information data re:-Urethra/Catheter Wall Pressure/Urethra Catheter operating Diameters/Urine Voiding Pressure and Flow Rate/Bladder Pressure/ etc. and can be used to call the Nurse/Operate Alarms or in a Ward where there are a number of Patients Centrally Remote Tape Record the obtained information from all the Patients continuously for Medical Reference data and Statistical Information assessment giving Urethra Pressure / Catheter Diameter / Voiding Flow Time / Nurse attention.

Additionally if a Patient is suffering from an Inflamed Urethra Wall and cannot tolerate an inflated usual size Urinary Control Device within the Urethra the Involuntary Voiding of Urine can be still controlled by using the basic Sphincter Urethra

Claim 5 cont...

Pressure Control Device (C2)(16E)Ø within the Catheter Tube (15) externally to the Urethra with the same components and functional operational purpose.

The portion of the Catheter Device support tube remaining in the Urethra simply comprising two small bore flexible Rubber Tubes (6 and 36) being used for the same purposes as previously described the third tube (C4)(18)Ø required for inflating the Sphincter Simulation Urethra Muscle Pressure Balloon (C2)(16E)Ø terminating in the externally (15) catheter located Urinary Incontinence Control Inflation Device (C2)(16E)Ø and both the internal two support tubes (6&36) being contained within the Thin Wall Collapsible Catheter Tube (TWF11C)(C3)(13)Ø within the Urethra Pressure Control area and which is directly attached to the support Bladder Balloon at the Top End and the external portion of the Catheter containing the (UICD)

The Urethra internal diameter is consequently reduced to a minimum for (98%) of the time, and is only inflated (2%) of the time when Urinating with less trauma to the Patient.

Claim 6

As claimed in Claims 1, 2, 3, 4 & 5

Incorporating a small bore diameter flexible Plastic or Rubber Tube (36) which may be used separately for some Patients not incontinent but with an Inflamed Urethra Tissue or attached in Parallel to the other two small bore diameter flexible rubber tubes (6) (18)ϕ for Patients who more usually and additionally may be incontinent and require a complete Urinary Incontinent and Voluntary Voiding Control Device (1SSUMPB)(C1)(16)ϕ

This tube is attached externally to an Anti-Biotic Gas/Liquid media supply Aerosol (MVUCS)(C5)(26) or a Hypodermic Syringe supply Capsule End (27) operated by the Nurse as required from which Anti Bacteria Media (C5) (26) is directly injected through the small bore diameter flexible rubber tube (36) into and via the other outlet end which is extended the whole length of the Urethra terminating slightly into the Urine Bladder.

The Urethra portion of this tube has holes pierced or perforated through its wall with the whole length laying within the Urethra and partly into the Bladder for venting (AB) spray (GLFM)(AB)(C5)(26) onto the whole of the Urethra and a small amount within the Baldder.

This (AB) media (C5) (26) should be used by the Patient after every Urination to eliminate the possibility of malignant Bacteria migration via the Urethra into the Kidneys and is automatically applied by the (MVUCS)(C6)(34'35) switch

Claim 6 cont...

If a Patient who is not incontinent has an inflamed tissue Urethra this single small bore tube (36) can be used on its own to spray Anti Biotic Gas/Liquid media within the whole Urethra by the Nurse as the Doctor specifies until the Urethra heals also this single tube (36) device would need to be attached to a second tube (6) with an attached Bladder Balloon support (4) suspension device on its top Bladder end (3) to locate and retain the Urethra (GLFM)(AB)(C5)(26) Spray Tube (36) in its functional location while being used as is usual within the Urethra.

With Immobile Incontinent Patients using a long external Catheter extension Urine Voiding Tube (15) because they need personal assistance which is not immediately available they may have to have a Urine Storage Container temporarily attached. When the Urine Storage bag is removed the Catheter Exit end to which has an attached Female Luer End in it would be plugged directly onto the Male Luer outlet (27) end of Anti-Biotic Spray Aerosol (26/37) to which it would remain attached during the Non Urination Periods of Time. The end of an Immobile Incontinent Patients external extension Catheter may have additionally if required inside it and retained therein an Anti Biotic impregnated porous Capsule ceramic or plastic with a hole passing through its central longitudinal axis to enable voiding urine to flow through unimpeded when Urinating, supplying slowly a continuous exudation

Claim 6 cont...

of an Anti-Baterial (C5) (26) material within the Catheter at all times which would remain within when not urinating.

Claim 7

A Claim as in Claims 1 to 6.

A device substantially as described herein with reference to Figs. 1 to 16 of the accompanying drawings.

Patents Act 1977
Examiner's report to the Comptroller under Section 17 (The Search Report)

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**Relevant Technical fields**

(i) UK Cl (Edition L ) A5R (RAC,RAM,RAR,RGA,REY)

(ii) Int Cl (Edition 5 ) A61F

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**Databases** (see over)
(i) UK Patent Office

(ii) ONLINE DATABASE: WPI

Date of Search
17 FEBRUARY 1993

Documents considered relevant following a search in respect of claims 1-7

| Category (see over) | Identity of document and relevant passages | Relevant to claim(s) |
|---|---|---|
| A | US 4961725 (REY ET AL) see line 12 column 3 - line 11 column 4 and line 19 column 6 - line 11 column 7 | 1 |

| Category | Identity of document and relevant passages | Relevant to claim(s. |
|---|---|---|
| | | |

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